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Monday
October 7, 1996

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Presidential Documents

Title 3—

The President

Proclamation 6925 of October 3, 1996

Suspension of Entry as Immigrants and Nonimmigrants of Persons Who Formulate or Implement Policies That Are Impeding the Transition to Democracy in Burma or Who Benefit From Such Policies

By the President of the United States of America

A Proclamation

The current regime in Burma continues to detain significant numbers of duly elected members of parliament, National League for Democracy activists, and other persons attempting to promote democratic change in Burma. The regime has failed to enter into serious dialogue with the democratic opposition and representatives of the country's ethnic minorities, has failed to move toward achieving national reconciliation, and has failed to meet internationally recognized standards of human rights.

In light of this continuing political repression, I have determined that it is in the interests of the United States to restrict the entrance into the United States as immigrants and nonimmigrants of certain Burmese nationals who formulate or implement policies that impede Burma's transition to democracy or who benefit from such policies, and the immediate families of such persons.

NOW, THEREFORE, I, WILLIAM J. CLINTON, by the power vested in me as President by the Constitution and the laws of the United States of America, including sections 212(f) and 215 of the Immigration and Nationality Act of 1952, as amended (8 U.S.C. 1182(f), 1185), and section 301 of title 3, United States Code, hereby find that the unrestricted immigrant and nonimmigrant entry into the United States of persons described in section 1 of this proclamation would, except as provided for in section 2 or 3 of this proclamation, be detrimental to the interests of the United States. I therefore, do proclaim that:

Section 1. The entry into the United States as immigrants and nonimmigrants of persons who formulate, implement, or benefit from policies that impede Burma's transition to democracy, and the immediate family members of such persons, is hereby suspended.

Sec. 2. Section 1 shall not apply with respect to any person otherwise covered by section 1 where the Secretary of State determines that the entry of such person would not be contrary to the interests of the United States. Section 1 shall not apply to officials assigned to Burmese missions in the United States or working-level support staff and visitors who support the work of Burmese missions in the United States.

Sec. 3. Persons covered by sections 1 and 2 shall be identified pursuant to procedures established by the Secretary of State, as authorized in section 6 below.

Sec. 4. Nothing in this proclamation shall be construed to derogate from United States Government obligations under applicable international agreements.

Sec. 5. This proclamation is effective immediately and shall remain in effect until such time as the Secretary of State determines that it is no longer necessary and should be terminated.

Sec. 6. The Secretary of State shall have responsibility to implement this proclamation pursuant to procedures the Secretary may establish. The Secretary of State may subdelegate the authorities set forth herein as he deems necessary and appropriate to implement this proclamation.

Sec. 7. This proclamation may be repealed, in whole or in part, at such time as the Secretary of State determines that the Burmese regime has released National League for Democracy members currently being held for political offenses and other pro-democracy activists, enters into genuine dialogue with the democratic opposition, or makes significant progress toward improving the human rights situation in the country.

IN WITNESS WHEREOF, I have hereunto set my hand this third day of October, in the year of our Lord nineteen hundred and ninety-six, and of the Independence of the United States of America the two hundred and twenty-first.

William J. Clinton

[FR Doc. 96–25917
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Rules and Regulations

Federal Register
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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 JUSTICE

Immigration and Naturalization Service

8 CFR Part 274a

[INS No. 1738–95]

RIN 1115–AE21

Employer Sanctions Modifications; Warning Notices; Generation of Blank Employment Eligibility Verification Forms (Forms I–9)

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Interim rule with request for comments.

SUMMARY: This rule amends the Immigration and Naturalization Service (Service) regulations by allowing the Service to issue a Warning Notice to employers in those cases where the Service has determined that a person or entity has violated section 274A of the Immigration and Nationality Act (the Act). The Warning Notice will be issued in those cases generally characterized by the identification of minor verification violations and the expectation of future compliance by the violator. This amendment is necessary to state expressly current Service policy and practice regarding the issuance of a Warning Notice in lieu of a Notice of Intent to Fine. This rule will also allow employers to generate blank copies of the Employment Eligibility Verification Form (Form I–9) electronically and provides for single-sided reproduction of the Form I–9, as well as the currently permitted double-sided reproduction. This is intended to save employers the cost of purchasing Forms I–9 and the burden of making double-sided copies of the form.

DATES: This interim rule is effective October 7, 1996. Written comments must be submitted on or before November 6, 1996.

ADDRESSES: Please submit written comments, in triplicate, to the Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, 425 I Street, NW., Room 5307, Washington, DC 20536. To ensure proper handling, please reference INS number 1738–95 on your correspondence. Comments are available for public inspection at the above address by calling (202) 514–3048 to arrange for an appointment.

FOR FURTHER INFORMATION CONTACT: Angelo V. Sorrento, Senior Special Agent, Investigations Division, Immigration and Naturalization Service, 425 I Street NW., Room 1000, Washington, DC 20536, telephone (202) 514–0747.

SUPPLEMENTARY INFORMATION:

Background

Over the past year, the Service has been reviewing its employer sanctions policies and procedures to facilitate employer compliance with the law and to improve enforcement efforts. This rule is part of the Service's effort to achieve that goal.

Regulatory Changes

The Service's regulations require all employers to complete Forms I–9, as evidence of verification of the identify and employment eligibility of each employee hired after November 6, 1986. Currently, the regulations permit the use of a Form I–9 which has been printed by the Superintendent of Documents, reproduced by public or private entities, or electronically generated, in accordance with the requirements set forth in 8 CFR 299.4.

This rule amends 8 CFR 274a.2 by allowing employers to electronically generate blank Forms I–9, provided that the resulting form is legible; there is no change to the name, content, or sequence of the data elements and instructions; no additional data elements or language are inserted; and the paper used meets the standards for retention and production for inspection specified under § 274a.2(b). When copying or printing the Form I–9, the text of the two-sided form may be reproduced in either double-sided or single-sided copies.

The Service is also amending 8 CFR 274a.9 to allow the Service to either issue and serve a Notice of Intent to Fine (NIF), Form I–763, upon an alleged violator after the Service has determined that the person or entity has violated section 274A of the Act, or issue a Warning Notice, Form I–846, for minor verification violations in those cases where the Service expects future compliance by the violator. A Warning Notice notifies employers that they are not in full compliance with the immigration laws relating to employment. The expectation is that, after issuance of the Warning Notice, the relatively minor violations will be corrected by the employer and not repeated. Employers served with a Warning Notice will benefit by avoiding fines normally levied by the issuance of a NIF. This rule will bring the regulations into conformance with existing Service policy and will allow the Service to issue a Warning Notice in lieu of a NIF and the Department of Labor to continue to issue Warning Notices.

The Service's implementation of this rule as an interim rule, with a 60-day provision for post-promulgation public comments, is based upon the ''good cause'' exceptions found at 5 U.S.C. 553 (b)(B) and (d)(1). The reasons and the necessity are as follows: this rule relieves a restriction and is beneficial to both public and private entities by facilitating employer compliance with the immigration laws.

Regulatory Flexibility Act

The Commissioner of the Immigration and Naturalization Service, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that the rule will not have a significant economic impact on a substantial number of small entities for the following reasons: This rule is intended to allow for the relief of fines on small entities for minor verification violations contained in section 274A of the Act. This rule also reduces an employer's burden of procuring Forms I–9 by allowing for the blank electronic generation of this form in single-sided copies.

Exeuctive Order 12866

This rule is not considered by the Immigration and Naturalization Service to be a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review, and the Office of Management and

Budget has waived its review process under section 6(a)(3)(A).

Executive Order 12612

The regulations adopted herein will not have substantial different 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 12612, it is determined that this rules does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 8 CFR Part 274a

Administrative practice and procedure, Alien employment, Penalties, Reporting and recordkeeping requirements.

Accordingly, part 274a of chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 274a—CONTROL OF EMPLOYMENT OF ALIENS

1. The authority citation for part 274a continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1324a; 8 CFR part 2.

2. In § 274a.2 paragraph, (a) is amended by revising the fifth and sixth sentences to read as follows:

§ 274a.2 Verification of employment eligibility.

(a) *General.* * * * Employers may electronically generate blank Forms I–9, provided that: the resulting form is legible; there is no change to the name, content, or sequence of the data elements and instructions; no additional data elements or language are inserted; and the paper used meets the standards for retention and production for inspection specified under § 274a.2(b). When copying or printing the Form I–9, the text of the two-sided form may be reproduced by making either double-sided or single-sided copies. * * *

* * * * *

3. Section 274a.9 is amended by:

a. Revising the third sentence of paragraph (b);

b. Redesignating paragraphs (c), (d), and (e) as paragraphs (d), (e) and (f) respectively; and

c. Adding a new paragraph (c), to read as follows:

§ 274a.9 Enforcement procedures.

* * * * *

(b) *Investigation.* * * * If it is determined after investigation that the person or entity has violated section 274A of the Act, the Service may issue and serve a Notice of Intent to Fine or a Warning Notice upon the alleged violator. * * *

(c) *Warning notice.* The Service and/or the Department of Labor may in their discretion issue a Warning Notice to a person or entity alleged to have violated section 274A of the Act. This Warning Notice will contain a statement of the basis for the violations and the statutory provisions alleged to have been violated.

* * * * *

Dated: August 8, 1996.

Doris Meissner,

Commissioner, Immigration and Naturalization Service.

[FR Doc. 96–25659 Filed 10–4–96; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 92

[Docket No. 95–054–2]

Importation of Horses from CEM Countries

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations regarding the importation of horses from countries affected with contagious equine metritis by incorporating new testing and treatment protocols for mares and stallions, providing for the use of accredited veterinarians to monitor horses temporarily imported into the United States for competition purposes, incorporating a new testing protocol for thoroughbred horses in training in their country of origin, and removing the requirements for endometrial cultures and clitoral sinusectomies in mares. These changes will update, clarify, and streamline the existing regulations and will simplify the requirements for importing horses from countries affected with contagious equine metritis without increasing the risk of the disease being introduced into or disseminated within the United States.

EFFECTIVE DATE: November 6, 1996.

FOR FURTHER INFORMATION CONTACT: Dr. Joyce Bowling, Staff Veterinarian, Import/Export Animals, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231, (301) 734–6479; or E-mail: jbowling@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 92 (referred to below as the regulations) prohibit or restrict the importation of certain animals into the United States to prevent the introduction of communicable diseases of livestock and poultry. Subpart C—Horses, §§ 92.300 through 92.326 of the regulations, pertains to the importation of horses into the United States. Sections 92.301 and 92.304 of the regulations contain specific provisions for the importation and post-entry handling of horses from countries affected with contagious equine metritis (CEM), a highly contagious bacterial venereal disease.

On June 4, 1996, we published in the Federal Register (61 FR 28073–28085, Docket No. 95–054–1) a proposal to amend the regulations by:

- Reorganizing the CEM regulations to eliminate duplication and to make their provisions easier to find and use;
- Removing the requirements for clitoral sinusectomies and endometrial cultures in female horses and establishing new protocols for the collection of specimens for culturing;
- Incorporating new testing and treatment protocols for stallions and test mares;
- Incorporating a new testing protocol for thoroughbred horses in training in their country of origin; and
- Providing for the use of accredited veterinarians to monitor horses from CEM-affected countries that are temporarily in the United States for competition purposes.

We solicited comments concerning our proposal for 60 days ending August 5, 1996. We received eight comments by that date. They were from a horse transporter/customs house broker, a State veterinarian, two private practice veterinarians, two thoroughbred owners/breeders associations, a horse industry council, and the director of a CEM quarantine facility. All of the commenters supported the proposed rule, although six of them offered suggestions or sought clarification regarding the changes proposed in the proposed rule. Those comments are discussed below.

Collection of Specimens

In the proposed rule, we proposed that for all mares over 731 days of age offered for importation or in quarantine in an approved State, specimens would be collected from the mucosal surfaces of the urethra, clitoral sinuses, and cervix. Six of the commenters disagreed with those proposed collection sites for two main reasons: (1) The commenters

pointed out that experience in Europe and the United States has shown the clitoral fossa, including the clitoral sinuses, to be the site from which the CEM organism is most likely to be located, and (2) the commenters all expressed reservations about the collection of specimens from the cervix of pregnant mares, given the risk of infection or even abortion that could result from swabbing that site. Based on those considerations, the commenters suggested that the urethra and cervix be eliminated as collection sites and that the clitoral fossa be added as a collection site. We agree with the reasoning and suggestions of the commenters and have, therefore, changed the collection sites for samples from female horses in this final rule. Specifically, we have changed the testing requirements for female thoroughbred horses in § 92.301(d)(1)(ii)(D), mares over 731 days of age in § 92.301(e)(1)(iii), and test mares in §§ 92.301(e)(3)(i)(B), 92.301(e)(4)(ii), and 92.301(e)(5)(i) to require that specimens for culturing be collected from the clitoral fossa and clitoral sinuses.

Treatment in Country of Origin

We had proposed to remove certain specific treatment instructions for stallions diagnosed with CEM in their country of origin and replace them with the requirement that the stallion be treated for CEM in a manner approved by the national veterinary service of the country of origin. One commenter was concerned that the treatment protocols used in a stallion's country of origin may not be as demanding as those that would be required by the Animal and Plant Health Inspection Service (APHIS) and thus may not eliminate the CEM organism; rather, the commenter suggested, the stallions should be treated in a manner approved in the country of destination, i.e., the United States.

As noted in the proposed rule, the treatments performed in the country of origin and the dates of the treatments will have to be recorded on the horse's health certificate, so APHIS will have the opportunity to consider the treatments used when the stallion is offered for importation into the United States. Further, we will continue to require that the stallion be retested no less than 21 days following the completion of treatment and found free of CEM before it will be eligible to enter the United States. Because that retesting requirement will be in place, we believe that allowing the national veterinary service of the country of origin to use its discretion in deciding the appropriate treatment for stallions that have been found to be positive for CEM will not result in an increased risk of CEM-infected stallions entering the United States. We have not, therefore, made any changes in response to that comment.

Treatment and Cleaning Protocol

The proposed rule also included a proposed protocol for the treatment and cleaning of the clitoral sinuses of mares over 731 days of age imported into an approved State. The protocol involved the flushing of the clitoral sinuses with a cerumalytic agent, followed by 5 days of cleaning the external genitalia and vaginal vestibule, including the clitoral fossa, with a solution of not less than 2 percent chlorhexidine in a detergent base and then filling the clitoral fossa and sinuses, and coating the external genitalia and vaginal vestibule, with an antibiotic ointment effective against the CEM organism. Three of the commenters were concerned that the 5 consecutive days of cleaning and coating would be irritating and even painful to a mare and would likely result in the mare violently resisting the treatment, which would pose a risk of injury to both the mare and the person doing the cleaning and possibly result in the procedure not being completed properly. Two commenters suggested that if the cleaning procedure were conducted properly and thoroughly, the period of treatment could be reduced to 3 or even 2 days.

The researchers who developed the cleaning and treatment procedure described above concluded that the cleaning and flushing of the clitoral sinuses should be followed by 5 consecutive days of washing and application of ointment to ensure that the treatment is effective. We will, therefore, retain the requirement for 5 days of post-flush treatment. We acknowledge that a mare undergoing the treatment may well become anxious or irritated as a result of the repeated handling of the genitalia and thus require restraint or anesthesia; if that is the case, the quarantine center personnel would be able to note the change in the mare's disposition and take whatever precautions they deem necessary to prevent any harm coming to them and to the mare. If subsequent research indicates that the procedure should be modified to reduce the length of treatment or increase its effectiveness, we will publish a new proposed rule in the Federal Register to modify the procedure. We have not, however, made any changes to the procedure in this final rule.

Clitoral Sinusectomy

We had proposed to eliminate the requirement that certain mares undergo a clitoral sinusectomy because the availability of procedures for the cleaning and treatment of the clitoral sinuses to eliminate the CEM organism had rendered clitoral sinusectomies unnecessary. One commenter did not agree and recommended that the clitoral sinusectomy be retained for use on mares that had tested positive for CEM, rather than depending on the cleaning and treatment procedure to eliminate the CEM organism. The cleaning and treatment procedure, the commenter suggested, could be retained for use on mares that had tested negative for CEM.

We have full confidence in the efficacy of the procedures described in the proposed rule for flushing and cleaning the clitoral sinuses, cleaning and washing the external genitalia and vaginal vestibule, and filling the clitoral fossa and sinuses and coating the external genitalia and vaginal vestibule with an antibiotic ointment effective against the CEM organism. This procedure has been shown to effectively eliminate debris that could harbor the CEM organism, which we believe renders clitoral sinusectomies in all mares, whether they have been diagnosed with CEM or not, unnecessary. We have, therefore, made no changes in response to that comment.

High-Risk Mares

Two commenters suggested that mares that had been diagnosed with and treated for CEM in their country of origin prior to importation into the United States should be classified as ''high-risk mares.'' The commenters did not recommend that any additional restrictions be placed on such mares, but only that APHIS notify the animal health authorities in the approved State to which a high-risk mare has been consigned when the mare is released from CEM quarantine.

Under the provisions of the regulations, a mare cannot be imported into the United States from a CEM country until a set of specimens has been collected from the mare and cultured negative for CEM. Once the mare has been imported into the United States and released from Federal port-of-entry quarantine, specimens must be collected from that mare three more times over a 7-day period and cultured, all with negative results. The mare must then undergo the cleaning and treatment procedure described in the previous paragraphs. Only after the mare has satisfied all those requirements may it

be released from quarantine. With these requirements in place, we are confident that any mare released from quarantine will be free from CEM; in that case, one mare would not present a higher risk than another. We do not believe, therefore, that it is necessary to differentiate between mares that have not been diagnosed with CEM and mares that were diagnosed with and effectively treated for CEM prior to their importation into the United States, so we have made no changes to this rule in response to that comment.

Use of Accredited Veterinarians

Two commenters supported the idea of allowing accredited veterinarians to conduct the monitoring required for horses imported for no more than 90 days to compete in specified events, but the commenters suggested that the accredited veterinarians be required to undergo some type of additional training to ensure that they are fully versed in the regulations regarding such temporary importations.

The monitoring required by § 92.301(f)(2)(ii) is to ensure that the horse is kept on a premises approved by an APHIS representative; is kept, except when actually competing or being exercised, in a stall that prevents any contact with other horses; and has no sexual contact with other horses and does not undergo any genital examinations. As noted in the proposed rule, an accredited veterinarian must be familiar with APHIS' animal health programs and regulations in order to be approved by the Administrator to perform the functions associated with those programs, and any accredited veterinarian monitoring temporarily imported horses would be subject to spot checks by an APHIS representative. Although we do not believe that accredited veterinarians will need to receive any additional training, as suggested by the commenter, we believe it would be useful for the APHIS Veterinarian in Charge in the State where the monitoring would take place to check with the accredited veterinarian to make sure that he or she is conversant in the duties and responsibilities associated with the monitoring of temporarily imported horses. We have, therefore, modified § 92.301(f)(2)(ii) in this final rule to state that the Veterinarian in Charge will ensure that the accredited veterinarian is familiar with the requirements of the regulations with regard to monitoring temporarily imported horses.

Release from Quarantine

One commenter sought clarification in three areas regarding the timing or sequence of certain testing and treatment requirements for stallions and mares in quarantine. First, the commenter asked whether the release of a stallion from quarantine would be a set number of days after it entered quarantine or if the release would be contingent upon the receipt of the results of the complement fixation test conducted 15 days after breeding on the two test mares. The regulations in § 92.301(e)(3)(iii) state that a stallion may be released from quarantine only if all cultures and tests of specimens from the mares used for test breeding are negative for CEM and all cultures performed on specimens taken from the stallion are negative for CEM. Because the results of all tests and cultures must be negative before the stallion can be released from quarantine, the release of a stallion from quarantine would indeed be contingent upon the receipt of the results of the complement fixation tests.

The commenter also noted that because many imported stallions have no previous breeding experience, it often takes several days to train them to safely breed a mare. Under the provisions described in the proposed rule, the stallion is test bred to two mares after it has been cultured negative for CEM, which the commenter speculated could be as soon as the stallion's first day in quarantine. The commenter recommended, therefore, that some flexibility should be built into the regulations to allow the quarantine facility staff sufficient time to train imported stallions to safely breed the test mares. Because there is no set time limit in the regulations for the completion of the test breeding, the flexibility sought by the commenter is, in fact, already present. The regulations in § 92.301(e)(3)(i) require only that the test breeding take place after negative results have been obtained from the stallion's CEM cultures, which is usually at least 2 or 3 days after the collection of specimens. If an imported stallion requires training to safely breed a mare, there is nothing in the regulations to prevent a quarantine facility's staff from taking the time necessary to conduct that training.

Finally, the commenter asked that we clarify the sequence of the actions described in the proposed rule under § 92.301(e)(5), ''Testing and treatment requirements for mares.'' The commenter was uncertain as to whether the washing and packing of the mare's external genitalia and vaginal vestibule was to be conducted prior to, or concurrent with, the collection of specimens from the mare on days one, four, and seven of quarantine. Actually, the washing and packing is to be after the three sets of specimens have been collected. The required actions are listed sequentially in § 92.301(e)(5): Collect three sets of specimens over 7 days, then clean and flush the sinuses, then wash and pack for 5 consecutive days. The commenter's confusion could be due to a lack of clarity at the start of § 92.301(e)(5)(ii), which begins ''Following the collections of specimens * * *'' without specifying that all three sets of specimens must be collected before the cleaning and flushing of the clitoral sinuses begins. In order to eliminate that potential source of confusion, we have modified the language in § 92.301(e)(5) in this final rule to make it clear that the collection of specimens is to be completed prior to the cleaning and flushing.

Another instance where a lack of clarity could lead to confusion is in § 92.301(d)(3). That paragraph states that thoroughbred horses found free from CEM and imported under § 92.301(d)(1) may be released after completing the Federal quarantine required under § 92.308; the paragraph does not, however, specify the post-entry requirements for thoroughbred horses over 731 days of age that were found positive for CEM and subsequently treated and retested for CEM as provided by § 92.301(d)(2). It was our intent when drafting the proposed rule that such thoroughbred horses, as is required for all other horses over 731 days of age that have been found positive for CEM and subsequently treated and retested for CEM, should be consigned to an approved State for post-entry testing and treatment. We have, therefore, modified the language in § 92.301(d)(3) to make it clear that thoroughbred horses over 731 days of age that have been treated and retested for CEM in accordance with § 92.301(d)(2) must undergo post-entry quarantine in an approved State.

In addition to the changes discussed above, we have also made several nonsubstantive editorial changes for the sake of clarity or consistency.

Therefore, based on the rationale set forth in the proposed rule and in this document, we are adopting the provisions of the proposal as a final rule, with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This rule amends the regulations regarding the importation of horses from countries affected with CEM by incorporating new testing and treatment protocols for mares and stallions, providing for the use of accredited veterinarians to monitor horses temporarily imported into the United States for competition purposes, incorporating a new testing protocol for thoroughbred horses in training in their country of origin, and removing the requirements for endometrial cultures and clitoral sinusectomies in mares. These changes will update, clarify, and streamline the existing regulations and simplify the requirements for importing horses from countries affected with CEM without increasing the risk of the disease being introduced into or disseminated within the United States.

The United States is a net exporter of horses, exporting approximately two horses for every one imported, and unit values for imports and exports slightly favored the United States during fiscal year (FY) 1994 and FY 1995. The unit value of exports was $3,762 per head in FY 1994, while the unit import value was $3,336 per head; in FY 1995, these values shifted to $2,742 per head (export) and $2,674 per head (import).

In FY 1994, U.S. exports of horses totaled 62,064 head valued at $233.4 million; in FY 1995, the total was 81,487 head valued at $223.4 million. Most of those horses were exported to Canada, Mexico, and Western Europe (especially the United Kingdom and Ireland). U.S. imports of horses, on the other hand, are small relative to total inventory and equal about half of U.S. horse exports. In FY 1994, U.S. horse imports totaled 17,881 head valued at $59.6 million; in FY 1995, the total was 43,545 head valued at $116.4 million. Canada and Mexico were the source of over 90 percent of all U.S. horse imports in those years. In each year, those imports equaled approximately 1 percent of the domestic horse inventory (USDA, Economic Research Service, ''Foreign Agricultural Trade of the United States,'' Fiscal Year 1995 Supplement). Small entities maintain almost 95 percent of the domestic horse inventory.

The new testing and treatment protocols presented in this document are the only aspects of this rule that are expected to have an economic impact. In each case, the changes will reduce the time required to collect samples, conduct tests, and administer treatments, which will shorten the period that an imported horse will have to spend in quarantine. Because the importer or owner of an imported horse must bear the cost of providing care, feeding, and handling of the horse during the time it is quarantined for CEM testing and treatment in an approved State, a shorter quarantine period will clearly reduce an owner's or importer's boarding costs. The current course of testing and treatment runs, on average, from 4 to 6 weeks; the testing and treatment protocols in this rule are expected to cut that time frame to 2 to 3 weeks.

We do not expect, however, that these changes will result in an increase of horse imports into the United States. Those countries that can already profitably ship horses to the United States and meet the current requirements of the regulations will not be significantly affected, and those countries that do not currently meet those requirements are not expected to meet the new requirements either.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Regulatory Reform

This action is part of the President's Regulatory Reform Initiative, which, among other things, directs agencies to remove obsolete and unnecessary regulations and to find less burdensome ways to achieve regulatory goals.

List of Subjects in 9 CFR Part 92

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 92 is amended as follows:

PART 92—IMPORTATION OF CERTAIN ANIMALS AND POULTRY AND CERTAIN ANIMAL AND POULTRY PRODUCTS; INSPECTION AND OTHER REQUIREMENTS FOR CERTAIN MEANS OF CONVEYANCE AND SHIPPING CONTAINERS THEREON

1. The authority citation for part 92 continues to read as follows:

Authority: 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 102–105, 111, 114a, 134a, 134b, 134c, 134d, 134f, 135, 136, and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(d).

2. In § 92.300, the definition of *Weanling or yearling* is revised to read as follows:

§ 92.300 Definitions.

* * * * *

Weanling or yearling. Any horse, weaned from its dam, that was foaled not more than 731 days prior to its being offered for entry into the United States. A horse will not be considered to be a weanling or yearling if its first permanent incisors have erupted.

§§ 92.303 and 92.304 [Amended]

3. Sections 92.303 and 92.304 are amended as follows:

a. In § 92.304, footnote 12 and its reference in the section heading are removed.

b. In § 92.303(e), footnote 11 and its reference are redesignated as footnote 12.

4. In § 92.301, paragraph (c) is revised and new paragraphs (d) through (i) are added to read as follows:

§ 92.301 General prohibitions; exceptions.

* * * * *

(c) *Specific prohibitions regarding contagious equine metritis; exceptions—(1) Importation prohibited.* Except as provided in paragraph (c)(2) of this section, notwithstanding the other provisions of this part concerning the importation of horses into the United States, the importation of all horses from any of the following listed countries and the importation of all horses that have been in any listed country within the 12 months immediately preceding their being offered for entry into the United States is prohibited, either because contagious equine metritis (CEM) exists in the listed country or because the listed country trades horses freely with a country in which CEM exists without testing for CEM: Austria, Belgium, Bosnia and Herzegovina, Croatia, Czech Republic, Denmark, Finland, France, Germany, Guinea-Bissau, Ireland, Italy,

Japan, the Member States of the European Union, The Netherlands, Norway, Slovakia, Slovenia, Sweden, Switzerland, The Former Yugoslav Republic of Macedonia, the United Kingdom (England, Northern Ireland, Scotland, Wales, and the Isle of Man), and the nonrecognized areas of the former Yugoslavia (Montenegro and Serbia).

Note: Montenegro and Serbia have asserted the formation of a joint independent State entitled ''The Federal Republic of Yugoslavia,'' but this entity has not been formally recognized by the United States.

(2) *Exceptions.* The provisions of paragraph (c)(1) of this section shall not apply to the following:

(i) Wild (non-domesticated) species of equidae if captured in the wild or imported from a zoo or other facility where it would be unlikely that the animal would come in contact with domesticated horses used for breeding;

(ii) Geldings;

(iii) Weanlings or yearlings whose age is certified on the import health certificate required under § 92.314(a);

(iv) Horses imported in accordance with conditions prescribed by the Administrator as provided in § 92.301(a);

(v) Thoroughbred horses imported for permanent entry from France, Germany, Ireland, or the United Kingdom if the horses meet the requirements of paragraph (d) of this section;

(vi) Stallions or mares over 731 days of age imported for permanent entry if the horses meet the requirements of paragraph (e) of this section;

(vii) Horses over 731 days of age imported into the United States for no more than 90 days to compete in specified events if the horses meet the requirements of paragraph (f) of this section; and

(viii) Horses temporarily exported from the United States or from another country not known to be affected with CEM to a country listed in paragraph (c)(1) of this section within the 12 months immediately preceding their being offered for entry into the United States if the horses meet the requirements of paragraph (g) of this section.

(d) *Thoroughbred horses from France, Germany, Ireland, and the United Kingdom.* (1) Thoroughbred horses may be imported for permanent entry from France, Germany, Ireland, or the United Kingdom if the horses meet the following requirements:

(i) Each horse is accompanied at the time of importation by an import permit in accordance with § 92.304;

(ii) Each horse is accompanied at the time of importation by an import health certificate issued in accordance with § 92.314(a). In addition to the information required by § 92.314(a), the veterinarian signing and issuing the certificate shall certify that:

(A) He or she has examined the daily records of the horse's activities maintained by the trainer and certified to be current, true, and factual by the veterinarian in charge of the training or racing stable;

(B) He or she has examined the records of the horse's activities maintained by a breed association specifically approved by the Department[6] and certified by the breed association to be current, true, and factual for the following information: Identification of the horse by name, sex, age, breed, and all identifying marks; identification of all premises where the horse has been since reaching 731 days of age and the dates that the horse was at such premises; and that none of the premises are breeding premises;

(C) He or she has compared the records maintained by the approved breed association with the records kept by the trainer and has found the information in those two sets of records to be consistent and current;

(D) For thoroughbred horses over 731 days of age, cultures negative for CEM were obtained from sets of specimens collected on 3 separate occasions within a 7-day period from the mucosal surfaces of the clitoral fossa and the clitoral sinuses of any female horses and from the surfaces of the prepuce, the urethral sinus, and the fossa glandis, including the diverticulum of the fossa glandis, of any male horses. For both female and male horses, the sets of specimens must be collected on days 1, 4, and 7 of the 7-day period, and the last of these sets of specimens must be collected within 30 days of exportation. All specimens required by this paragraph must be collected by a licensed veterinarian who either is, or is acting in the presence of, the veterinarian signing the certificate; and

(E) All specimens required by paragraph (d)(1)(ii)(D) of this section were received within 48 hours of collection by a laboratory approved to culture for CEM by the national veterinary service of the country of export and were accompanied by a statement indicating the date and time of their collection.

(2) If any specimen collected in accordance with paragraph (d)(1)(ii)(D) of this section is found to be positive for CEM, the horse must be treated for CEM in a manner approved by the national veterinary service of the country of export. After the treatment is completed, at least 21 days must pass before the horse will be eligible to be tested again in accordance with paragraph (d)(1)(ii)(D) of this section. All treatments performed, and the dates of the treatments, must be recorded on the health certificate.

(3) Thoroughbred horses imported under paragraph (d)(1) of this section may be released upon completion of the Federal quarantine required under § 92.308. Thoroughbred horses found positive for CEM that have been treated and retested as provided in paragraph (d)(2) of this section shall, upon completion of the Federal quarantine required under § 92.308, be consigned to an approved State listed in paragraph (h)(6) or (h)(7) of this section, where they shall be quarantined under State or Federal supervision until the stallions have met the testing and treatment requirements of paragraph (e)(3) of this section and the mares have met the testing and treatment requirements of paragraph (e)(5) of this section.

(e) *Stallions and mares over 731 days of age from CEM-affected countries.* (1) Stallions or mares over 731 days of age may be imported for permanent entry from a country listed in paragraph (c)(1) of this section if the horses meet the following requirements:

(i) Each horse is accompanied at the time of importation by an import permit issued in accordance with § 92.304. The import permit must indicate that, after completion of the Federal quarantine required in § 92.308, the stallion or mare will be consigned to a State that the Administrator has approved to receive such horses in accordance with paragraph (h) of this section;

(ii) The horses are accompanied at the time of importation by an import health certificate issued in accordance with § 92.314(a);

(iii) A set of specimens must be collected from each horse within 30 days prior to the date of export by a licensed veterinarian who either is, or is acting in the presence of, the veterinarian signing the certificate. For stallions, the specimens must be collected from the prepuce, urethral sinus, and fossa glandis, including the diverticulum of the fossa glandis; for mares, the specimens must be collected from the mucosal surfaces of the clitoral fossa and the clitoral sinuses. All of the specimens collected must be cultured for CEM with negative results in a laboratory approved to culture for CEM

[6] The following breed associations and their record systems have been approved by the Department: Weatherby's Ltd. for the United Kingdom and Ireland; Haras du Pain for France; and Direktorium für Vollblutzucht und Rennen e.v. for Germany.

by the national veterinary service of the country of origin;

(iv) The horses described on the certificate must not have been used for natural breeding, for the collection of semen for artificial insemination in the case of stallions, or for artificial insemination in the case of mares, from the time the specimens were collected through the date of export;

(v) All specimens required by paragraph (e)(1)(iii) of this section must be received within 48 hours of collection by a laboratory approved to culture for CEM by the national veterinary service of the country of export and must be accompanied by a statement indicating the date and time of their collection; and

(vi) If any specimen collected in accordance with paragraph (e)(1)(iii) of this section is found to be positive for CEM, the stallion or mare must be treated for CEM in a manner approved by the national veterinary service of the country of export. After the treatment is completed, at least 21 days must pass before the horse will be eligible to be tested again in accordance with paragraph (e)(1)(ii) of this section. All treatments performed, and the dates of the treatments, must be recorded on the health certificate.

(2) *Post-entry.* (i) Stallions and mares imported under paragraph (e)(1) of this section must complete the Federal quarantine required under § 92.308. Upon completion of the Federal quarantine, stallions must be sent to an approved State listed in paragraph (h)(6) of this section, and mares must be sent to an approved State listed in paragraph (h)(7) of this section.

(ii) Once in the approved State, the stallions or mares shall be quarantined under State or Federal supervision until the stallions have met the testing and treatment requirements of paragraph (e)(3) of this section and the mares have met the testing and treatment requirements of paragraph (e)(5) of this section.

(iii) All tests and cultures required by paragraphs (e)(3) through (e)(5) of this section shall be conducted at the National Veterinary Services Laboratories, Ames, IA, or at a laboratory approved by the Administrator in accordance with paragraph (i) of this section to conduct CEM cultures and tests.

(iv) To be eligible for CEM culture or testing, all specimens collected in accordance with paragraphs (e)(3) through (e)(5) of this section must be received by the National Veterinary Services Laboratories or the approved laboratory within 48 hours of collection and must be accompanied by a statement indicating the date and time of their collection.

(3) *Testing and treatment requirements for stallions.* (i) Once the stallion is in the approved State, one specimen each shall be taken from the prepuce, the urethral sinus, and the fossa glandis, including the diverticulum of the fossa glandis, of the stallion and be cultured for CEM. After negative results have been obtained, the stallion must be test bred to two test mares that meet the requirements of paragraph (e)(4) of this section. Upon completion of the test breeding:

(A) The stallion must be treated for 5 consecutive days by thoroughly cleaning and washing (scrubbing) its prepuce, penis, including the fossa glandis, and urethral sinus while the stallion is in full erection with a solution of not less than 2 percent surgical scrub chlorhexidine and then thoroughly coating (packing) the stallion's prepuce, penis, including the fossa glandis, and urethral sinus with an ointment effective against the CEM organism.[7] The treatment shall be performed by an accredited veterinarian and monitored by a State or Federal veterinarian.

(B) Each mare to which the stallion has been test bred shall be cultured for CEM from sets of specimens that are collected from the mucosal surfaces of the clitoral fossa and clitoral sinuses on the third, sixth, and ninth days after the breeding, with negative results. A complement fixation test for CEM must be done with negative results on the fifteenth day after the breeding.

(ii) If any culture or test required by this paragraph is positive for CEM, the stallion shall be treated as described in paragraph (e)(3)(i)(A) of this section and retested by being test bred to two mares no less than 21 days after the last day of treatment.

(iii) A stallion may be released from State quarantine only if all cultures and tests of specimens from the mares used for test breeding are negative for CEM and all cultures performed on specimens taken from the stallion are negative for CEM.

(4) *Requirements for test mares.* (i) Mares to be used to test stallions for CEM shall be permanently identified before the mares are used for such testing with the letter ''T.'' The marking shall be permanently applied by an inspector, a State inspector, or an accredited veterinarian who shall use a hot iron, freezemarking, or a lip tattoo. If a hot iron or freezemarking is used, the marking shall not be less than 2 inches (5.08 cm) high and shall be applied to the left shoulder or left side of the neck of the mare. If a lip tattoo is used, the marking shall not be less than 1 inch (2.54 cm) high and 0.75 inch (1.9 cm) wide and shall be applied to the inside surface of the upper lip of the test mare.

(ii) The test mares must be qualified prior to breeding as apparently free from CEM and may not be used for breeding from the time specimens are taken to qualify the mares as free from CEM. To qualify, each mare shall be tested with negative results by a complement fixation test for CEM, and specimens taken from each mare shall be cultured negative for CEM. For culture, sets of specimens shall be collected on the first, fourth, and seventh days of a 7-day period from the mucosal surfaces of the clitoral fossa and clitoral sinuses.

(iii) A test mare that has been used to test stallions for CEM may be released from quarantine only if:

(A) The test mare is found negative for CEM on all cultures and tests required under paragraph (e)(3)(ii) of this section; or

(B) The test mare is subjected to an ovariectomy by an accredited veterinarian under the direct supervision of a State or Federal veterinarian; or

(C) The test mare is treated and handled in accordance with paragraph (e)(5) of this section; or

(D) The test mare is moved directly to slaughter without unloading en route, is euthanized, or dies.

(5) *Testing and treatment requirements for mares.* (i) Once the mare is in the approved State, sets of specimens shall be collected from the mare on three separate occasions within a 7-day period. On days 1, 4, and 7, an accredited veterinarian shall collect specimens from the mucosal surfaces of the clitoral fossa and clitoral sinuses and shall submit each set of specimens to the National Veterinary Services Laboratories, Ames, IA, or to a laboratory approved by the Administrator in accordance with paragraph (i) of this section to conduct CEM cultures and tests.

(ii) After the three sets of specimens required by paragraph (e)(5)(i) of this section have been collected, an accredited veterinarian shall manually remove organic debris from the sinuses of each mare and then flush the sinuses with a cerumalytic agent.[8]

[7] A list of ointments effective against the CEM organism may be obtained from the National Center for Import and Export, Import/Export Animals, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231.

[8] Recommended protocols for the flushing of sinuses may be obtained from the National Center

Continued

(iii) For 5 consecutive days after the sinuses have been cleaned, an accredited veterinarian shall aseptically clean and wash (scrub) the external genitalia and vaginal vestibule, including the clitoral fossa, with a solution of not less than 2 percent chlorhexidine in a detergent base and then fill the clitoral fossa and sinuses, and coat the external genitalia and vaginal vestibule with an antibiotic ointment effective against the CEM organism.[9]

(iv) A mare may be released from State quarantine only if all cultures performed on specimens taken from the mare are negative for CEM.

(v) If any culture required by this paragraph is positive for CEM, the mare shall be treated as described in paragraphs (e)(5)(ii) and (e)(5)(iii) of this section. No less than 21 days after the last day of treatment, the mare shall be tested again in accordance with paragraph (e)(5)(i) of this section. If all specimens are negative for CEM, the mare may be released from quarantine.

(f) *Special provisions for temporary importation.* Horses over 731 days of age may be imported into the United States for no more than 90 days to compete in specified events if the following conditions are met:

(1) The horse may remain in the United States for not more than 90 days following the horse's arrival in the United States, except as provided in paragraph (f)(6) of this section and, while in the United States, the horse must be moved according to the itinerary and methods of transport specified in the import permit provided for in § 92.304 of this part;

(2) While the horse is in the United States, the following conditions must be met:

(i) Except when in transit, the horse must be kept on a premises that has been approved, orally or in writing, by an APHIS representative. If the approval is oral, it will be confirmed in writing by the Administrator as soon as circumstances permit. To receive approval, the premises:

(A) Must not be a breeding premises; and

(B) Must be or contain a building in which the horse can be kept in a stall that is separated from other stalls containing horses, either by an empty stall, by an open area across which horses cannot touch each other, or by a solid wall that is at least 8 feet (2.4 m) high.

(ii) While at the premises at which the horse competes, the horse must be monitored by an accredited veterinarian or APHIS representative to ensure that the provisions of paragraphs (f)(2)(i), (f)(2)(iv), and (f)(2)(v) of this section are met. If the monitoring is performed by an accredited veterinarian, the Veterinarian in Charge will ensure that the accredited veterinarian is familiar with the requirements of this section and spot checks will be conducted by an APHIS representative to ensure that the requirements of this section are being met. If an APHIS representative finds that requirements are not being met, the Administrator may require that all remaining monitoring for the event be conducted by APHIS representatives to ensure compliance.

(iii) While in transit, the horse must be moved in either an aircraft or a sealed van or trailer. If the horse is moved in a sealed van or trailer, the seal may be broken only by an APHIS representative at the horse's destination, except in situations where the horse's life is in danger.

(iv) Except when actually competing or being exercised, the horse must be kept in a stall that is separated from other stalls containing horses, either by an empty stall, by an open area across which horses cannot touch each other, or by a solid wall that is at least 8 feet (2.4 m) high.

(v) The horse may not be used for breeding purposes (including artificial insemination), may not have any other sexual contact with other horses, and may not undergo any genital examinations.

(vi) After the horse is transported anywhere in the United States, any vehicle in which the horse was transported must be cleaned and disinfected in the presence of an APHIS representative, according to the procedures specified in §§ 71.7 through 71.12 of this chapter, before any other horse is transported in the vehicle.

(vii) The cleaning and disinfection specified in paragraph (f)(2)(vi) of this section must be completed before the vehicle is moved from the place where the horse is unloaded. In those cases where the facilities or equipment for cleaning and disinfection are inadequate at the place where the horse is unloaded, the Administrator may allow the vehicle to be moved to another location for cleaning and disinfection when the move will not pose a disease risk to other horses in the United States.

(viii) The owner or importer of the horse must comply with any other provisions of this part applicable to him or her.

(3) If the owner or importer wishes to change the horse's itinerary or the methods by which the horse is transported from that which he or she specified in the application for the import permit, the owner or importer must make the request for change in writing to the Administrator. Requests should be sent to the Administrator, c/o Import-Export Animals Staff, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231. The change in itinerary or method of transport may not be made without the written approval of the Administrator, who may grant the request for change when he or she determines that granting the request will not endanger other horses in the United States and that sufficient APHIS personnel are available to provide the services required by the owner or importer. If more than one application for an import permit is received, APHIS personnel will be assigned in the order that the applications that otherwise meet the requirements of this section are received.

(4) The Administrator may cancel, orally or in writing, the import permit provided for under § 92.304 of this part whenever the Administrator finds that the owner or importer of the horse has not complied with the provisions of paragraphs (f)(1) through (f)(3) of this section or any conditions imposed under those provisions. If the cancellation is oral, the Administrator will confirm the cancellation and the reasons for the cancellation in writing as soon as circumstances permit. Any person whose import permit is canceled may appeal the decision in writing to the Administrator within 10 days after receiving oral or written notification of the cancellation, whichever is earlier. If the appeal is sent by mail, it must be postmarked within 10 days after the owner or importer receives oral or written notification of the cancellation, whichever is earlier. The appeal must include all of the facts and reasons upon which the person relies to show that the import permit was wrongfully canceled. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator.

(5) Except in those cases where an appeal is in process, any person whose import permit is canceled must move the horse identified in the import permit out of the United States within 10 days after receiving oral or written

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for Import and Export, Import/Export Animals, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231.

[9] A list of ointments effective against the CEM organism may be obtained from the National Center for Import and Export, Import/Export Animals, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231.

notification of cancellation, whichever is earlier. The horse is not permitted to enter competition from the date the owner or importer receives the notice of cancellation until the horse is moved out of the United States or until resolution of an appeal in favor of the owner or importer. Except when being exercised, the horse must be kept, at the expense of the owner or importer, in a stall on the premises where the horse is located when the notice of cancellation is received, or, if the horse is in transit when the notice of cancellation is received, on the premises where it is next scheduled to compete according to the import permit. The stall in which the horse is kept must be separated from other stalls containing horses, either by an empty stall, by an open area across which horses cannot touch each other, or a by solid wall that is at least 8 feet (2.4 m) high. In cases where the owners of the above specified premises do not permit the horse to be kept on those premises, or when the Administrator determines that keeping the horse on the above specified premises will pose a disease risk to horses in the United States, the horse must be kept, at the expense of the owner or importer, on an alternative premises approved by the Administrator.

(6) Stallions or mares over 731 days of age that are imported for no more than 90 days in accordance with paragraphs (f)(1) through (f)(3) of this section may be eligible to remain in the United States if the following is completed:

(i) Following completion of the itinerary specified in the import permit provided for in § 92.304 of this part, the horse's owner or importer applies for and receives a new import permit that specifies that the stallion or mare will be moved to an approved State listed in paragraph (h)(6) or (h)(7) of this section; and

(ii) The stallion or mare is transported in a sealed vehicle that has been cleaned and disinfected to an approved facility in an approved State where it is quarantined under State or Federal supervision until the stallion or mare has met the testing and treatment requirements of paragraph (e)(3) or (e)(5) of this section.

(7) All costs and charges associated with the supervision and maintenance of a horse imported under paragraphs (f)(1) through (f)(3) of this section will be borne by the horse's owner or importer. The costs associated with the supervision and maintenance of the horse by an APHIS representative at his or her usual places of duty will be reimbursed by the horse's owner or importer through user fees payable under part 130 of this chapter.

(8) In the event that an APHIS representative must be temporarily detailed from his or her usual place of duty in connection with the supervision and maintenance of a horse imported under paragraphs (f)(1) through (f)(3) of this section, the owner or importer of the horse must execute a trust fund agreement with APHIS to reimburse all expenses (including travel costs, salary, per diem or subsistence, administrative expenses, and incidental expenses) incurred by the Department in connection with the temporary detail. Under the trust fund agreement, the horse's owner or importer must deposit with APHIS an amount equal to the estimated cost, as determined by APHIS, for the APHIS representative to inspect the premises at which the horse will compete, to conduct the monitoring required by paragraph (f)(2)(ii) of this section, and to supervise the cleaning and disinfection required by paragraph (f)(2)(vi) of this section. The estimated costs will be based on the following factors:

(i) Number of hours needed for an APHIS representative to conduct the required inspection and monitoring;

(ii) For services provided during regular business hours (8 a.m. to 4:30 p.m., Monday through Saturday, except holidays), the average salary, per hour, for an APHIS representative;

(iii) For services provided outside regular business hours, the applicable rate for overtime, night differential, or Sunday or holiday pay, based on the average salary, per hour, for an APHIS representative;

(iv) Number of miles from the premises at which the horse competes to the APHIS office or facility that is monitoring the activities;

(v) Government rate per mile for automobile travel or, if appropriate, cost of other means of transportation between the premises at which the horse competes and the APHIS office or facility;

(vi) Number of trips between the premises at which the horse competes and the APHIS office or facility that APHIS representatives are required to make in order to conduct the required inspection and monitoring;

(vii) Number of days the APHIS representative conducting the inspection and monitoring must be in ''travel status;''

(viii) Applicable government per diem rate; and

(ix) Cost of related administrative support services.

(9) If a trust fund agreement with APHIS has been executed by the owner or importer of a horse in accordance with paragraph (f)(8) of this section and APHIS determines, during the horse's stay in the United States, that the amount deposited will be insufficient to cover the services APHIS is scheduled to provide during the remainder of the horse's stay, APHIS will issue to the horse's owner or importer a bill to restore the deposited amount to a level sufficient to cover the estimated cost to APHIS for the remainder of the horse's stay in the United States. The horse's owner or importer must pay the amount billed within 14 days after receiving the bill. If the bill is not paid within 14 days after its receipt, APHIS will cease to perform the services provided for in paragraph (f)(2) of this section until the bill is paid. The Administrator will inform the owner or importer of the cessation of services orally or in writing. If the notice of cessation is oral, the Administrator will confirm, in writing, the notice of cessation and the reason for the cessation of services as soon as circumstances permit. In such a case, the horse must be kept, at the expense of the owner or importer and until the bill is paid, in a stall either on the premises at which the horse is located when the notice of cessation of services is received, or, if the horse is in transit when the notice of cessation of services is received, on the premises at which it is next scheduled to compete according to the import permit. The stall in which the horse is kept must be separated from other stalls containing horses either by an empty stall, an open area across which horses cannot touch each other, or a solid wall that is at least 8 feet (2.4 m) high. In cases where the owners of the above specified premises do not permit the horse to be kept on those premises, or when the Administrator determines that keeping the horse on the above specified premises will pose a disease risk to other horses in the United States, the horse must be kept, at the expense of the owner or importer, on an alternative premises approved by the Administrator. Until the bill is paid, the horse is not permitted to enter competition. Any amount deposited in excess of the costs to APHIS to provide the required services will be refunded to the horse's owner or importer.

(g) *Special provisions for the importation of horses that have been temporarily exported to a CEM-affected country.* If a horse has been temporarily exported for not more than 60 days from the United States to a CEM-affected country listed in paragraph (c)(1) of this section, or if a horse has been temporarily exported for not more than 60 days from another country not

known to be affected with CEM to a CEM-affected country during the 12 months preceding its exportation to the United States, the horse may be eligible for return or importation into the United States without meeting the requirements of paragraphs (d) through (f) of this section under the following conditions:

(1) The horse must be accompanied by a certificate that meets the requirements of § 92.314(a) of this part issued by each CEM-affected country that the horse has visited during the term of its temporary exportation, and each certificate must contain the following additional declarations:

(i) That the horse was held separate and apart from all other horses except for the time it was actually participating in an event or was being exercised by its trainer;

(ii) That the premises on which the horse was held were not used for any equine breeding purpose;

(iii) That the horse was not bred to or bred by any animal, nor did it have any other sexual contact or genital examination while in such country; and

(iv) That all transport while in such country was carried out in cleaned and disinfected vehicles in which no other horses were transported since such cleaning and disinfection;

(2) The horse is accompanied by an import permit issued in accordance with § 92.304 of this part at the time of exportation;

(3) If the horse was temporarily exported from the United States and is being returned to the United States, the horse must be accompanied by a copy of the United States health certificate issued for its exportation from the United States and endorsed in accordance with the export regulations in part 91 of this chapter;

(4) The horse must be examined by an inspector at the U.S. port of entry and found by the inspector to be the identical horse covered by the documents required by paragraphs (a) through (c) of this section and found by the inspector to be free of communicable disease and exposure thereto; and

(5) The horse must be quarantined and tested at the U.S. port of entry as provided in § 92.308 of this part prior to release.

(h) *Approval of States.* In order for a State to be approved to receive stallions or mares over 731 days of age from a CEM-affected country listed in paragraph (c)(1) of this section that are imported under paragraph (e) of this section, the State must meet the following conditions:

(1) The State must enter into a written agreement with the Administrator, whereby the State agrees to enforce its laws and regulations to control CEM and to abide by the conditions of approval established by the regulations in this part.

(2) The State must agree to quarantine all stallions and mares over 731 days of age imported under the provisions of paragraph (e) of this section until the stallions have been treated in accordance with paragraph (e)(3) of this section and the mares have been treated in accordance with paragraph (e)(5) of this section.

(3) The State must agree to quarantine all mares used to test stallions for CEM until the mares have been released from quarantine in accordance with paragraph (e)(4) of this section.

(4) The State must have laws or regulations requiring that stallions over 731 days of age imported under paragraph (e) of this section be treated in the manner specified in paragraph (e)(3) of this section, and that mares over 731 days of age imported under paragraph (e) of this section be treated in the manner specified in paragraph (e)(5) of this section.

(5) Approval of any State to receive stallions or mares imported from countries affected with CEM may be suspended by the Administrator upon his or her determination that any requirements of this section are not being met. After such action is taken, the animal health authorities of the approved State will be informed of the reasons for the action and afforded an opportunity to present their views thereon before such suspension is finalized; however, such suspension of approval shall continue in effect unless otherwise ordered by the Administrator. In those instances where there is a conflict as to the facts, a hearing shall be held to resolve such conflict.

(6) The following States have been approved to receive stallions over 731 days of age imported under paragraph (e) of this section:

The State of Alabama
The State of California
The State of Colorado
The State of Florida
The State of Kentucky
The State of Louisiana
The State of Maryland
The State of Montana
The State of New Hampshire
The State of New Jersey
The State of New York
The State of North Carolina
The State of Ohio
The State of South Carolina
The State of Tennessee
The State of Texas
The State of Virginia
The State of Wisconsin

(7) The following States have been approved to receive mares over 731 days of age imported under paragraph (e) of this section:

The State of Alabama
The State of California
The State of Colorado
The State of Kentucky
The State of Louisiana
The State of Maryland
The State of Montana
The State of Hew Hampshire
The State of New Jersey
The State of New York
The State of North Carolina
The State of Ohio
The State of South Carolina
The State of Tennessee
The State of Texas
The State of Virginia
The State of Wisconsin

(i) *Approval of laboratories.* (1) The Administrator will approve a laboratory to conduct CEM cultures and tests only after consulting with the State animal health official in the State in which the laboratory is located and after determining that the laboratory:

(i) Has technical personnel assigned to conduct the CEM culturing and testing who possess the following minimum qualifications:

(A) A bachelor's degree in microbiology;

(B) A minimum of 2 years experience working in a bacteriology laboratory; and

(C) Experience working with the CEM organism, including knowledge of the specific media requirements, atmospheric requirements, and procedures for the isolation and identification of the CEM organism.[10]

(ii) Follows standard test protocols that will reliably and consistently provide for the isolation and identification of the CEM organism;[11] and

(iii) Reports all official test results to the State animal health official and the Veterinarian in Charge.

(2) To retain approval, the laboratory must meet the requirements prescribed in paragraph (i)(1) of this section, and shall test with the CEM organism each lot of media it prepares to ensure that the media will support growth of the laboratory's reference culture. Media that will not support growth of the reference culture must be discarded.

[10] When training regarding CEM culturing and testing is necessary, it may be obtained at the National Veterinary Services Laboratories, Ames, IA 50010.

[11] Standard test protocols recommended by the National Veterinary Services Laboratories and a list of approved laboratories can be obtained from the National Veterinary Services Laboratories, Ames, IA 50010.

(3) The Administrator may deny or withdraw approval of any laboratory to conduct CEM culturing or testing upon a determination that the laboratory does not meet the criteria for approval or maintenance of approval under paragraphs (i)(1) and (i)(2) of this section.

(i) In the case of a denial of approval, the operator of the laboratory will be informed of the reasons for denial and, upon request, will be afforded an opportunity for a hearing with respect to the merits or validity of the denial in accordance with rules of practice that will be adopted for the hearing.

(ii) In the case of a withdrawal of approval, before such action is taken, the operator of the laboratory will be informed of the reasons for the proposed withdrawal and, upon request, will be afforded an opportunity for a hearing with respect to the merits or validity of the proposed withdrawal in accordance with rules of practice that will be adopted for the hearing. However, the withdrawal will become effective pending a final determination in the hearing when the Administrator determines that such action is necessary to protect the public health, interest, or safety. The withdrawal will be effective upon oral or written notification, whichever is earlier, to the operator of the laboratory. In the event of oral notification, written confirmation will be given as promptly as circumstances allow. The withdrawal will continue in effect pending completion of the hearing and any judicial review of the hearing, unless otherwise ordered by the Administrator.

(iii) Approval for a laboratory to conduct CEM culturing or testing will be automatically withdrawn by the Administrator when the operator of the approved laboratory notifies the National Veterinary Services Laboratories, Ames, IA 50010, in writing, that the laboratory no longer conducts CEM culturing and testing.

(Approved by the Office of Management and Budget under control number 0579–0040)

5. Section 92.304 is amended as follows:

a. The section heading is revised to read as set forth below.

b. In the introductory text of paragraph (a)(1)(ii), the reference ''§ 92.301(c)(2)(viii)'' is removed both times it appears and the reference ''§ 92.301(f)'' added in its place.

c. In paragraph (a)(1)(iii), in the first sentence, the reference ''§ 92.301(c)(2)(viii)'' is removed and the reference ''§ 92.301(f)'' added in its place.

d. Paragraphs (a)(4) through (a)(12) are removed.

e. Paragraph (b) is revised to read as set forth below.

§ 92.304 Import permits for horses from countries affected with CEM and for horse specimens for diagnostic purposes; reservation fees for space at quarantine facilities maintained by APHIS.

* * * * *

(b) *Permit.* (1) When a permit is issued, the original and two copies will be sent to the importer. It shall be the responsibility of the importer to forward the original permit and one copy to the shipper in the country of origin, and it shall also be the responsibility of the importer to ensure that the shipper presents the copy of the permit to the carrier and makes the necessary arrangements for the original permit to accompany the shipment to the specified U.S. port of entry for presentation to the collector of customs.

(2) Horses and horse test specimens for which a permit is required under paragraph (a) of this section will be received at the port of entry specified on the permit within the time prescribed in the permit, which shall not exceed 14 days from the first day that the permit is effective.

(3) Horses and horse test specimens for which a permit is required under paragraph (a) of this section will not be eligible for entry if:

(i) A permit has not been issued for the importation of the horse or horse test specimen;

(ii) If the horse or horse test specimen is unaccompanied by the permit issued for its importation;

(iii) If the horse or horse test specimen is shipped from any port other than the one designated in the permit;

(iv) If the horse or horse test specimen arrives in the United States at any port other than the one designated in the permit;

(v) If the horse or horse test specimen offered for entry differs from that described in the permit; or

(vi) If the horse or horse test specimen is not handled as outlined in the application for the permit and as specified in the permit issued.

§ 92.308 [Amended]

6. In § 92.308(a)(3), footnote 16 and its reference in the text are redesignated as footnote 14.

7. In § 92.308(c)(1), footnote 17 and its reference in the text are redesignated as footnote 15.

8. Section 92.314 is revised to read as follows:

§ 92.314 Horses, certification, and accompanying equipment.

(a) Horses offered for importation from any part of the world shall be accompanied by a certificate of a salaried veterinary officer of the national government of the country of origin, or if exported from Mexico, shall be accompanied either by such a certificate or by a certificate issued by a veterinarian accredited by the National Government of Mexico and endorsed by a full-time salaried veterinary officer of the National Government of Mexico, thereby representing that the veterinarian issuing the certificate was authorized to do so, showing that:

(1) The horses described in the certificate have been in said country during the 60 days preceding exportation;

(2) That each horse has been inspected on the premises of origin and found free of evidence of communicable disease and, insofar as can be determined, exposure thereto during the 60 days preceding exportation;

(3) That each horse has not been vaccinated with a live or attenuated or inactivated vaccine during the 14 days preceding exportation: *Provided, however,* that in specific cases the Administrator may authorize horses that have been vaccinated with an inactivated vaccine to enter the United States when he or she determines that in such cases and under such conditions as he or she may prescribe such importation will not endanger the livestock in the United States, and such horses comply with all other applicable requirements of this part;

(4) That, insofar as can be determined, no case of African horse sickness, dourine, glanders, surra, epizootic lymphangitis, ulcerative lymphangitis, equine piroplasmosis, Venezuelan equine encephalomyelitis, or equine infectious anemia has occurred on the premises of origin or on adjoining premises during the 60 days preceding exportation; and

(5) That, except as provided in § 92.301(g):

(i) The horses have not been in any country listed in § 92.301(c)(1) as affected with CEM during the 12 months immediately prior to their importation into the United States;

(ii) The horses have not been on any premises at any time during which time such premises were found by an official of the veterinary services of the national government of the country where such premises are located, to be affected with CEM;

(iii) The horses have not been bred by or bred to any horses from an affected premises; and

(iv) The horses have had no other contact with horses that have been found to be affected with CEM or with horses that were imported from countries affected with CEM.

(b) If a horse is presented for importation from a country where it has been for less than 60 days, the horse must be accompanied by a certificate that meets the requirements of paragraph (a) of this section that has been issued by a salaried veterinary officer of the national government of each country in which the horse has been during the 60 days immediately preceding its shipment to the United States. The dates during which the horse was in each country during the 60 days immediately preceding its exportation to the United States shall be included as a part of the certification.

(c) Following the port-of-entry inspection required by § 92.306 of this part, and before a horse offered for importation from any part of the world is released from the port of entry, an inspector may require the horse and its accompanying equipment to be disinfected as a precautionary measure against the introduction of foot-and-mouth disease or any other disease dangerous to the livestock of the United States.

9. Preceding § 92.315, in the undesignated center heading ''CANADA[18]'', footnote 18 and its reference are redesignated as footnote 16.

10. Preceding § 92.319, in the undesignated center heading ''COUNTRIES OF CENTRAL AMERICA AND WEST INDIES[19]'', footnote 19 and its reference are redesignated as footnote 17.

11. Preceding § 92.321, in the undesignated center heading ''MEXICO[20]'', footnote 20 and its reference are redesignated as footnote 18.

§ 92.324 [Amended]

12. In § 92.324, in the third sentence, footnote 21 and its reference in the text are redesignated as footnote 19.

Done in Washington, DC, this 2nd day of October 1996.

A. Strating,

Acting Administrator, Animal and Plant Health Inspection Service.

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FEDERAL RESERVE SYSTEM

12 CFR Part 213

[Regulation M; Docket No. R–0892]

Consumer Leasing

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is publishing a final rule to amend Regulation M, which implements the Consumer Leasing Act. The Act requires lessors to provide uniform cost and other disclosures about consumer lease transactions. The Board has reviewed Regulation M, pursuant to its policy of periodically reviewing its regulations, and has revised the regulation to carry out more effectively the purposes of the Act. The final rule adds disclosures, primarily in connection with motor vehicle leasing, including, for example, disclosures about early termination charges and how scheduled payments are derived (which requires disclosure of such items as the gross capitalized cost of a lease, the vehicle's residual value, the rent charge, and depreciation). General changes in the format of the disclosures require that certain leasing disclosures be segregated from other information. Revisions to the advertising provisions implement a statutory amendment, allowing a toll-free number to substitute for certain disclosures in radio and television advertisements, and make other changes to the advertising rules. A lessor is not required to disclose the cost of a lease expressed as a percentage rate; however, if a rate is disclosed or advertised, a special notice must accompany the rate. Further, a rate in an advertisement cannot be more prominent than any other Regulation M disclosure.

DATES: Effective date. October 31, 1996. *Compliance date.* Compliance is optional until October 1, 1997.

FOR FURTHER INFORMATION CONTACT: Kyung H. Cho-Miller, Obrea O. Poindexter, or W. Kurt Schumacher, Staff Attorneys, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, Washington, DC 20551, at (202) 452–2412 or 452–3667. For matters concerning the Regulatory Flexibility Analysis, in appendix I, contact Thomas A. Durkin, Office of the Secretary, Board of Governors of the Federal Reserve System, Washington, DC 20551, at (202) 452–2326. Users of Telecommunications Device for the Deaf *only* may contact Dorothea Thompson, at (202) 452–3544.

SUPPLEMENTARY INFORMATION:

I. Background on the Consumer Leasing Act and Regulation M

The Consumer Leasing Act (CLA), 15 U.S.C. 1667–1667e, was enacted into law in 1976 as an amendment to the Truth in Lending Act (TILA), 15 U.S.C. 1601 *et seq.* The Board was given rulewriting authority, and its Regulation M (12 CFR Part 213) implements the CLA. An official staff commentary interprets the regulation. (Supplement I to 12 CFR 213).

The CLA generally applies to consumer leases of personal property in which the contractual obligation does not exceed $25,000 and has a term of more than four months. An automobile lease is the most common type of consumer lease covered by the act. Leases accounted for about one-third of all passenger car deliveries to consumers in 1995. Leasing in the luxury-car market is estimated to account for more than 70 percent for some models. Used cars are also now being leased, although to date they account for a relatively small segment of the market.

Under the statute, prior to entering into a lease agreement, lessors must give consumers 15 to 20 disclosures, including the amount of initial, end-of-lease, and other charges to be paid by the consumer (such as security deposits, insurance premiums, disposition fees, and taxes); an identification of the leased property; a payment schedule; the responsibilities for maintaining the leased property; and the liability for terminating a lease early. Special provisions apply to open-end leases. These provisions regulate balloon payments by limiting liability at the end of a lease term to no more than three times the monthly payment, and also require several disclosures unique to open-end leases (in §§ 213.4 (k) and (m)).

Open-end leases are a very small segment of the consumer leasing market. In open-end leases, the consumer's liability at the end of the lease term is based on the difference between the residual value of the leased property and its realized value. The consumer—not the lessor—assumes the risk that the realized value may be less than what was initially estimated. Closed-end leases are the most common type of lease covered under the CLA and Regulation M. These leases are sometimes referred to as ''walk-away'' leases because the consumer is not liable for the difference between the residual and the realized values at the end of the lease term.

II. The Review of Regulation M

The Board's Regulatory Planning and Review Program calls for the periodic review of a regulation with four goals in mind: to clarify and simplify regulatory language; to determine whether regulatory amendments are needed to address technological and other developments; to reduce undue regulatory burden on the industry; and to delete obsolete provisions.

Advance Notice of Proposed Rulemaking. The Board began its review of Regulation M—the first substantial review of the regulation since it was issued in 1976—by publishing an advance notice of proposed rulemaking on November 19, 1993 (58 FR 61035). Although comment was solicited generally on all provisions of the regulation, the Board specifically sought comment on three issues: disclosure of early termination charges, broadcast media advertising of leases, and segregation of leasing disclosures from other information. Most of the 70 comment letters that were received commented only on the three issues addressed in the advance notice. The comment letters were received mostly from automobile lessors or their representatives, but also from federal and state government agencies and from consumer representatives. Most of the commenters supported revisions to the disclosures about early termination charges either to better alert consumers about such charges or to address concerns about lender liability associated with providing extremely complex disclosures about these charges. Some commenters supported more flexibility in the advertising rules, while others expressed concern about the manner in which leases are advertised. Many supported segregation of leasing disclosures from other information. In addition, many commenters urged the Board to mandate the disclosure of the ''capitalized cost'' of a lease, meaning the value of the leased vehicle and other items that are capitalized by agreement between the lessor and lessee.

The Proposed Rule to Revise Regulation M. The Board published a proposed rule to substantially revise Regulation M on September 20, 1995 (60 FR 48752) and an extension of comment period notice was published on December 6, 1995 (60 FR 62349). The proposal offered a new disclosure format for model forms and some substantive changes to the regulation. New disclosures were proposed pursuant to the Board's authority under § 105(a) of the TILA. Section 105(a) of the TILA provides that the Board's regulations ''may contain such classifications, differentiations, or other provisions, and may provide for such adjustments and exceptions for any class of transactions, as in the judgment of the Board are necessary or proper to effectuate the purposes of [the CLA], to prevent circumvention or evasion thereof, or to facilitate compliance therewith.''

The proposal contained the following proposed amendments to Regulation M:

Segregation of certain leasing disclosures. (Leasing disclosures were dispersed throughout a leasing contract.) Additionally, a statement would remind consumers to read their contracts for other important consumer leasing disclosures not included in the segregated disclosures.

Revision of the disclosure of upfront fees to make it easier for a consumer to understand the amounts to be paid and how they are allocated, including the amount of any trade-in allowance.

Disclosure of the ''gross cost'' (the agreed upon acquisition value of leased property) and the ''residual value'' (the estimated value at the end of the lease term).

Disclosure of an ''estimated lease charge,'' a figure similar in purpose to the finance charge in a credit transaction.

Disclosures about early termination charges—including a transaction-specific example of such a charge at an assumed termination point after one year—and about charges for excessive wear of leased property.

Changes to the advertising rules to implement a statutory amendment, simplify disclosure requirements, and deter misleading advertising.

About 150 comment letters were received on the Board's proposed rule, from consumer representatives involved in leasing issues and a large segment of the consumer leasing industry. A majority of the commenters generally supported the requirement that certain disclosures be segregated from the remaining disclosures and other information. Major industry representatives expressed concern, however, about the overall disclosure format and offered an alternative that presented some disclosures in a mathematical progression. Commenters generally supported additional disclosures but many of them suggested modifications to the Board's proposed definition of the estimated lease charge and the gross cost. While many commenters favored an early termination warning about charges for terminating a lease early, a large majority of them opposed the requirement of a transaction-specific numerical example for early termination.

To get direct feedback from individual consumers, in January 1996 the Board conducted four focus groups, two in the Washington, D.C. area and two in Los Angeles, California. Participants gave their opinions on various disclosure formats, including the Board's proposed model form, an alternative form showing a mathematical progression of how periodic payments are derived, and a format in which a few disclosures would be highlighted in boxes. There were a total of 32 participants (evenly representing men and women), about a quarter of whom had previously leased automobiles.

While focus group participants had some concerns about the layout and language in the disclosure statements presented, they responded more favorably to the mathematical progression format than to the Board's proposal. Some participants liked the payment calculation disclosure because it ''walked you through the process.'' Many of them were generally familiar with the highlighting of certain disclosures in credit transactions. For lease transactions, they expressed an interest in seeing the value of the car, the total due at lease signing, and the monthly payments highlighted.

The Final Rule Amending Regulation M. The final rule includes most of the disclosures to supplement the act that were contained in the proposed rule. The major changes primarily affect motor vehicle leasing. They include a mathematical progression on how the periodic payment is derived (using figures such as the gross capitalized cost, residual value, amount of depreciation and amortized amounts) and a warning statement about charges for terminating a lease early. Certain leasing disclosures must be segregated from other information.

The final rule contains revisions to the advertising provisions, including the implementation of a statutory amendment. The statute allows a toll-free number or a print advertisement to substitute for certain lease disclosures in radio commercials, and the final rule expands the application of this provision to television.

The Board had expressly solicited comment in the proposal about whether the regulation should require the disclosure of a lease rate. Under the final rule, a lessor is not required to disclose the cost of a lease expressed as a percentage rate. If a rate is disclosed or advertised, a notice must accompany the rate stating that the percentage may not measure the overall cost of financing the lease transaction. Also, in the case

of advertising, a rate cannot be more prominent than any other Regulation M disclosure.

Other changes have been made to clarify and update the regulation. Obsolete provisions have been deleted, and generally footnotes have been moved to the regulatory text or to the Official Staff Commentary to Regulation M.

The final rule contains the following major amendments to Regulation M:

A revised disclosure format.

A total of payments disclosure.

An itemization that shows the mathematical progression used to derive the periodic payment.

A strong narrative warning about the possibility of substantial charges for early termination.

A notice to accompany any percentage rate (to indicate the limitations of rate information).

Implementation of a statutory amendment for certain broadcast advertisements and other changes to the advertising rules.

Official Staff Commentary. When the Board published the proposed revisions to Regulation M for public comment, it also published proposed revisions to the Official Staff Commentary on September 20, 1995 (60 FR 48769). The Board will publish an updated proposal to the commentary in mid-November 1996. The proposal will include material that was published for comment in September 1995, incorporate guidance contained in the section-by-section discussion that accompanies this final rule, and address other questions that may be brought to the Board's attention following the public's review of the final rule.

III. Recommendations for Legislative Changes

In addition to seeking comment on the proposed regulatory changes, the Board's September 1995 notice solicited views on whether specific legislative revisions to the CLA may also be warranted. A few commenters suggested that CLA coverage be expanded to cover leases that exceed the current $25,000 cap, given the higher cost of automobiles.

IV. Effective Date

This final rule is effective October 31, 1996, but compliance is optional until October 1, 1997. The mandatory effective date is designated by section 105(d) of the act, which states that any regulation promulgated by the Board is effective October 1 of a given year, provided the rule was published at least six months in advance.

V. Section-by-Section Discussion of the Final Rule

The following discussion covers the revisions section-by-section. Changes that are self-evident, and text that has been simplified or clarified without substantive change, are generally not discussed. Captions have been added to each paragraph, to conform with current Board style; the addition or wording of captions alone is not meant as a substantive change in the meaning of the paragraph itself.

Section 213.1 Authority, Scope, Purpose, and Enforcement

Former paragraph 1(d) on the issuance of staff interpretations has been moved to appendix C.

1(b) Scope and Purpose

An introductory sentence has been added to state the scope of the law. This paragraph has been revised to more closely parallel the purpose clauses in § 102 of the TILA.

Section 213.2 Definitions

Certain definitions are redesignated or added as indicated below. Former section 213.2(b)—the rules of construction—has been deleted except that former paragraph 2(b)(1) has been moved to paragraph 2(e)(1) of this section. Former § 213.3—exempt transactions—has been moved to paragraph 2(e)(3) of this section.

Definition	Final rule
"Act" in former 213.2(a)(1).	213.2(a).
"Advertisement" in former 213.2(a)(2).	213.2(b); examples moved to commentary.
"Agricultural purpose" in former 213.2(a)(3).	Moved to commentary.
"Arrange for lease of personal property". in former 213.2(a)(4).	Moved to commentary.
"Board" in former 213.2(a)(5).	213.2(c).
"Closed-end lease" ...	213.2(d) new.
"Consumer lease" in former 213.2(a)(6).	213.2(e).
"Gross capitalized cost".	213.2(f) new.
"Lessee" in former 213.2(a)(7).	213.2(g).
"Lessor" in former 213.2(a)(8).	213.2(h).
"Open-end lease"	213.2(i) new.
"Organization" in former 213.2(a)(9).	213.2(j).
"Period" in former 213.2(a)(10).	Deleted as unnecessary.
"Person" in former 213.2(a)(11).	213.2(k).
"Personal property" in former 213.2(a)(12).	213.2(l).
"Real property" in former 213.2(a)(13).	Deleted as unnecessary.
"Realized value" in former 213.2(a)(14).	213.2(m).
"Residual value"	213.2(n) new.
"Security interest" in former 213.2(a)(15).	213.2(o); examples of security interests moved to the commentary.
"State" in former 213.2(a)(16).	213.2(p).
"Total lease obligation" in former 213.2(a)(17).	Deleted as unnecessary; open-end and closed-end terminology conformed.
"Value at consummation" in former 213.2(a)(18).	Deleted as unnecessary; open-end and closed-end terminology conformed.

2(b) Advertisement.

The definition of advertisement is simplified and the examples have been moved to the commentary. The definition of advertisement is broad, covering commercial messages in any medium, including electronic media such as the Internet, that directly or indirectly promote a lease transaction.

2(d) Closed-end lease.

A definition of a closed-end lease has been added, modeled after the definition of closed-end credit in Regulation Z (12 CFR § 226.2(a)(10)). The term covers any lease that does not fall within the definition of an open-end lease. Commenters generally favored having definitions of open- and closed-end leases.

2(e) Consumer lease.

The paragraph has been reorganized. The rule of construction in former § 213.2(b)(1) has been moved to paragraph (e)(1). Transactions not included in the definition of consumer lease are now in paragraph (e)(2). Former section § 213.3 on exempt transactions is now paragraph (e)(3). The term contractual obligation excludes refundable and ''pass-through'' amounts a lessee is obligated to pay. For example, the total contractual obligation does not include license and registration fees and taxes. It also does not include the residual value.

2(f) Gross capitalized cost.

A definition of gross capitalized cost has been added to this section. Only items capitalized or amortized by the lessor are included in this figure. The Board's proposal had contained a broader definition using the term gross cost. Commenters favored a narrower definition. Definitions of the related terms capitalized cost reduction and

adjusted capitalized cost have also been added to this section. The supplementary information to § 213.4(f)(1) provides a discussion of these terms and further discussion about the gross capitalized cost, including the disclosure of the agreed upon value.

2(h) Lessor.

The definition of lessor incorporates a numerical test similar to the test in Regulation Z for defining a creditor (see footnote 3 to 12 CFR 226.2(a)(17)). Commenters generally supported the revision. The phrase ''in the ordinary course of business'' has been omitted as unnecessary.

2(i) Open-end lease.

A definition of an open-end lease has been added. Disclosures in §§ 213.4(k) and (m) and § 213.7(d)(2)(vi) are only relevant to open-end leases.

2(n) Residual value.

A definition of residual value has been added. Many commenters urged the Board to clarify that the residual value is the lessor's assigned value of the vehicle used to calculate the lessee's monthly payments, and not necessarily a projection of the value of the car. Several lessors noted that often a value is assigned to accommodate promotional campaigns of a manufacturer. The final rule has a revised definition in accordance with these comments.

Section 213.3 General disclosure requirements.

The following sections are redesignated or added as indicated below:

Former	Final rule
213.4(a)(1)	213.3(a)(1).
213.4(a)(2)	213.3(a)(1); 3(a)(3). 213.3(a)(2) new.
213.4(a)(3)	213.3(a)(1).
213.4(a)(4)	213.3(a)(4).
213.4(b)	213.3(b).
213.4(c)	213.3(c).
213.4(d)	213.3(d).
213.4(e)	213.3(e).
213.4(f)	213.3(f).

Paragraph 3(a) contains general rules about the disclosures required under § 213.4, including the form, content, and timing of disclosures. Paragraph 3(f) on minor variations includes former comment 4(a)–2. The major revision to this section, discussed under paragraph 3(a)(2), is the requirement to segregate certain disclosures from other information. Clear and conspicuous lease disclosures must be given prior to consummation of a lease on a dated written statement that identifies the lessor and lessee.

3(a) *General requirements.*

Based on comments and to provide a standard consistent with that of other consumer regulations, the Board has added language requiring that disclosures be given in a form the consumer may keep.

3(a)(1) *Form of disclosures.*

Former §§ 213.4(a)(1) and 4(a)(2) required that all disclosures be made together on a separate statement or in the lease contract ''above the place for the lessee's signature.'' The Board has deleted this requirement along with the meaningful sequence, same-page, and type-size disclosure requirements, replacing them with the requirement that disclosures be segregated. Most commenters generally supported the proposed segregation requirement, although some commenters opposed the deletion of the other requirements. They believed that the signature requirement ensured that lessors would give disclosures before the consumer becomes obligated on the lease and discouraged lessors from putting important information on the back of a lease document. The Board believes that a segregation requirement and the clear and conspicuous standard provide the same level of protection as the previous rules.

The segregated disclosures and other CLA disclosures must be given to a consumer at the same time. Lessors must continue to ensure that the disclosures are given to lessees before the lessee becomes obligated on the lease transaction. For example, by placing disclosures that are included in the lease documents above the lessee's signature, or by including instructions alerting a lessee to read the disclosures prior to signing the lease.

Nonsegregated disclosures need not all be on the same page, but should be presented in a way that does not obscure the relationship of the terms to each other.

3(a)(2) *Segregation of certain disclosures.*

Most commenters—representing both the industry and consumer groups—generally supported some form of segregation of leasing disclosures. Many commenters believed that consumers would be more likely to read and understand the disclosures if key items were segregated from other disclosures and contract terms. Pursuant to its authority under section 105(a) of the TILA, the Board has adopted the requirement that certain consumer leasing disclosures be segregated from other required disclosures and from general contract terms to assure clear, conspicuous, and meaningful disclosure of lease terms.

Some commenters, including trade groups that represent a large portion of the motor vehicle leasing industry, suggested that the more important disclosures be further highlighted in a manner similar to the Board's Regulation Z. The Board believes that the segregation requirement and the requirement that disclosures be in a form substantially similar to the applicable model form in appendix A adequately focuses the consumer's attention on key information.

Lessors may provide the segregated disclosures on a separate document or may include them in their lease contracts, apart from other information. The general content, format, and headings for these disclosures should be substantially similar to those contained in the model forms in appendix A. Lessors may continue to provide the remaining disclosures required by Regulation M and the CLA in a nonsegregated format.

The model forms in Appendix A for open-end leases, closed-end leases, and furniture leases have been revised.

3(a)(4) *Language of disclosures.*

Under former § 213.4(a)(4), lease disclosures had to be provided in English, except in the Commonwealth of Puerto Rico, where they could be given in Spanish. The final rule revises this position. Lessors are permitted to give disclosures in another language as long as disclosures in English are given upon request. The Board believes that a more permissive rule promotes a more meaningful delivery of disclosures to consumers.

3(b) *Additional information; nonsegregated disclosures.*

Former § 213.4(b) permitted additional information to be included with any disclosures required by the regulation. The Board proposed to permit additional information only with the nonsegregated disclosures. Some commenters believed that the Board should permit the inclusion of state-required disclosures among the federally-required segregated disclosures. The Board believes that the purpose of segregating disclosures could be diluted if additional information is permitted among them. The final rule permits additional information only with the nonsegregated CLA leasing disclosures.

Former §§ 213.4(b)(1) and 4(b)(2) on inconsistent disclosures have been

deleted. Pursuant to § 186(a) of the CLA, § 213.9 addresses the preemption of state law if information required by state law is inconsistent with the requirements of the act or regulation.

3(c) *Multiple lessors or lessees.*

Paragraph 3(c) provides that when a transaction involves multiple lessors, one lessor may make the disclosures on behalf of all of them. The phrase ''and the one that discloses shall be the one chosen by the lessors'' has been deleted as unnecessary. No substantive change is intended.

3(d) *Use of estimates.*

Former § 213.4(d) on the use of estimated disclosures has been redesignated and simplified as paragraph 3(d). The last sentence of the former paragraph has been deleted as unnecessary.

3(e) *Effect of subsequent occurrence.*

The rule in paragraph 3(e), previously stated in former § 213.4(e), has been revised to add a reference to consummation, to clarify that this rule is limited to events occurring after consummation of a lease. Footnote 1 of the former regulation, containing a specific example of a subsequent occurrence, has been moved to the commentary except for the second sentence, which has been deleted as unnecessary.

3(f) *Minor variations.*

Paragraph 3(f) incorporates into the regulation the rules on minor variations that may be disregarded in making disclosures, including provisions formerly contained in comment 4(a)-2 of the staff commentary.

Section 213.4 Content of disclosures.

Although the regulation applies to leases of all types of personal property such as furniture, much of the focus of the Board's review under the Regulatory Planning and Review Program has been on motor vehicle leasing. Because the regulatory issues have arisen in this context, the final rule limits some of the new disclosure, formatting, and advertising requirements to leases for motor vehicles. This section has been reorganized essentially to follow the progression of disclosures in the model forms as follows:

Former	Final rule
213.4(g)(1)	213.4(a).
213.4(g)(2)	213.4(b).
213.4(g)(3)	213.4(c).
213.4(g)(4)	213.4(n).
213.4(g)(5)	213.4(d).
213.4(g)(6)	213.4(o).
213.4(g)(7)	213.4(p).
213.4(g)(8)	213.4(h); 4(h)(3) new.
213.4(g)(9)	213.4(r).
213.4(g)(10)	213.4(q).
213.4(g)(11)	213.4(i).
213.4(g)(12)	213.4(g); 4(g)(2) new.
213.4(g)(13)	213.4(k).
213.4(g)(14)	213.4(l).
213.4(g)(15)	213.4(m).
	213.4(e) new.
	213.4(f) new.
	213.4(j) new.
	213.4(s) new.

4(b) *Amount due at lease signing.*

Paragraph 4(b) requires lessors to disclose to consumers the total amount of any payment due at lease signing (consummation of the lease). The Board has adopted several revisions to this paragraph. The revised language provides that the total amount of payments due at lease signing must be itemized by amount as well as by type and included among the segregated disclosures under the heading ''amount due at lease signing.'' Previously, the lessor was required to itemize these charges by type but not by amount. Also, to enhance consumer understanding of the transaction, the lessor is required to itemize by type and amount ''how the amount due at lease signing will be paid,'' which typically includes any net trade-in allowance, rebate, noncash credits, and payments in cash. (See the model forms in appendix A for format.) The Board believes that the standardization of terminology and the full itemization of the amounts due and means of payment provide consumer benefit without imposing substantial compliance costs on lessors.

Commenters supported the proposal in substance. Most of the commenters supporting the proposal believed that the proposed side-by-side format would discourage unscrupulous lessors from failing to credit a lessee's downpayment or trade-in. Some industry representatives offered an alternative format using only one column to present the disclosure, in place of the ''balance sheet'' approach. Upon further analysis, the Board believes that the balance sheet approach, in which the two columns equal one another, is appropriate to ensure that the amounts of trade-ins, rebates, and cash payments are used to reduce the total amount due at lease signing.

Some commenters asked whether a rebate that is subtracted from the value of the vehicle in arriving at the gross capitalized cost needs to be disclosed and itemized under this paragraph. They also inquired about ''negative trade-ins.'' A rebate would be included in the itemization under this section only when it is applied against the amount due at lease signing. Also, where the amount owed on a prior loan or lease exceeds an agreed-upon trade-in value, the difference is reflected in the gross capitalized cost, and no trade in allowance would be reflected under the column ''how the amount due at lease signing is paid.''

4(d) *Other Charges*

In addition to the periodic payment, the regulation requires disclosure of a total of other charges and an itemization by type and amount, payable during and at the end of the lease term. The model forms include examples of such fees—for example, an annual tax and a disposition fee at the end of the lease term.

4(e) *Total of payments*

The Board adopted this disclosure to serve as a tool for comparing leases that involve the same or similar types of leased properties for the same lease duration. As the disclosure includes all payments the consumer is obligated to make under the lease, it is not meant to reflect the cost of financing the lease transaction.

This disclosure, accompanied by the statement ''the amount you will have paid by the end of the lease,'' is the net sum of the amount due at lease signing (excluding refundable amounts such as the security deposit), the total of periodic payments (excluding the first periodic payment, if paid at lease signing), and other charges are not part of the periodic payments (such as a disposition fee). An additional disclosure is required for open-end leases because, with some limitations, consumers are liable for the difference between the residual and realized values of the leased property.

4(f) *Payment calculation*

Many commenters on the Board's proposed rule expressed concern that the revised format of the Board's model disclosure form did not present information in a manner that would allow consumers to understand the relationship of lease terms such as the ''gross cost'' and the ''residual value'' of a lease. Representatives of major automobile leasing companies offered an alternative format, one that shows how the periodic payments are derived. They said that such a disclosure scheme would result in better consumer understanding of a lease transaction and would enable consumers to verify their periodic payment. These commenters

also noted that the disclosure would impose little additional compliance burden as lessors make this calculation in setting up a lease transaction.

The Board believes that a mathematical progression itemizing the components of the periodic payment is valuable to consumers. It enables consumers to see several of the newly required disclosures in the context of the calculation, thereby enhancing the consumer's understanding of the particular disclosures. Also, it allows consumers to verify their periodic payment amount.

The CLA does not call for a payment calculation, but based on the comments and on further analysis, the Board is exercising its rulemaking authority under § 105(a) of the TILA to require the disclosure of the amounts comprising the periodic payment, in motor vehicle leases, in a manner substantially similar to the model leasing forms in appendix A. The payment calculation utilizes several disclosures from the proposal; it requires the modification of others that were proposed, and adds new ones, as discussed below.

4(f)(1) *Gross capitalized cost*

In the past, federal law has not required disclosure of information on the base price of the leased property in closed-end leases. Because this figure has not typically been given, consumers often have assumed that the lease is based on the manufacturer's suggested retail price (MSRP), or on a sales price negotiated by the consumer (who might have initially contemplated financing or paying cash for the vehicle). If the lessor uses a different starting price in the lease payment computation, one that is higher than either the MSRP or the negotiated figure, the consumer would be unaware of that fact, and thus would not be aware that perhaps the periodic payment could be lower.

The Board's proposal would have required disclosure of the ''gross cost'' among the segregated disclosures. This disclosure would have been applicable only to closed-end leases, given that the regulation already required the disclosure of a comparable term—the ''value at consummation (the initial value)''—in open-end leases. Under the proposal, the Board would have defined the gross cost as ''the total dollar amount of all items included in the value of a lease at consummation.''

A large majority of the commenters supported the disclosure of the base price of the leased property in closed-end leases, in one form or another. However, many of the industry commenters strongly objected to using the term ''gross cost'' and objected also to the items that would be included in the definition. Most of these commenters recommended that the term be changed from ''gross cost'' to either ''gross capitalized cost'' or ''capitalized cost'' to conform with state law (as several states now require the disclosure of this figure) and also to conform with industry practice. Trade associations that represent a large segment of the industry have encouraged their members to voluntarily disclose the ''capitalized cost,'' and some lessors have been doing so. Industry commenters suggested that the term ''capitalized cost'' has gained a certain amount of acceptance from consumers. Finally, both leasing representatives and consumer interest groups believed that the disclosed figure should reflect only the amounts that are *capitalized* by the lessor (such as the price of the leased property on which the lease is based); and, in particular, believed that it should not include amounts that are paid at lease signing by the consumer.

In response to the comments and upon further analysis, the Board has modified the final rule to require the disclosure of the ''gross capitalized cost,'' using that term, in both closed-end and open-end motor vehicle leases. Only items capitalized or amortized by the lessor are to be included. The gross capitalized cost is readily available to lessors from worksheets they use in setting the terms and conditions of the lease, and hence the Board believes that this disclosure requirement will not be unduly burdensome for lessors.

Some commenters representing consumer interests asked that the capitalized cost figure be itemized to give the consumer a clear picture of the base price of the leased automobile and other amounts being financed, such as an outstanding balance from a prior loan or lease. They suggested that without a breakdown, consumers could easily misunderstand what is included or excluded from the capitalized cost disclosure. A few industry commenters believed that disclosing an itemization would be burdensome for lessors; they also believed an itemization would have to be quite detailed to provide adequate guidance to lessees concerning the treatment of specific costs.

The final rule requires a disclosure of the gross capitalized cost with a description such as ''the agreed upon value of the vehicle [state the amount] and any items you pay over the lease term (such as service contracts, insurance, and any outstanding prior loan or lease balance).'' The ''agreed upon value'' of the motor vehicle means the amount for the vehicle agreed upon by the lessor and the lessee for purposes of the lease. This would include capitalized items such as the following: charges for vehicle accessories and options, delivery or destination charges, and rustproofing. The lessor could also include taxes and fees for license, title, and registration. The ''value'' would not include charges for service or maintenance contracts, insurance products, gap waivers, or an outstanding balance on a prior lease or loan.

Based on comments and upon further analysis, the Board believes that disclosure of the gross capitalized cost (including the agreed upon value) may aid consumers in better understanding lease pricing. The final rule also allows the consumer to obtain an itemization of the gross capitalized cost upon request. (See the model form in appendix A.) As in the case of Regulation Z, the itemization must be given separately, not within the segregated disclosures.

The Board solicited comment on whether the gross cost—the first item on the proposed model form—should be de-emphasized or removed from the required disclosures to avoid potential manipulation of the figure by lessors to mislead consumers. The few commenters that addressed the issue thought that the potential risk is negligible.

4(f)(2) *Capitalized cost reduction.*

The Board's proposed rule required the disclosure of any ''capitalized cost reduction'' in the disclosure of the total amount due at lease signing. Like a downpayment in the case of a credit transaction, the capitalized cost reduction reduces the capitalized cost and thus the periodic payments. In response to comments, the final rule requires that any capitalized cost reduction be reflected both in the disclosure of the amount due at lease signing and in the mathematical progression of the periodic payment amount.

4(f)(3) *Adjusted capitalized cost.*

In response to the comments, the final rule requires the disclosure of the ''adjusted capitalized cost,'' which equals the gross capitalized cost less any capitalized cost reduction. This net figure is the starting point for determining the periodic payment of the lease.

4(f)(4) *Residual value.*

The Board proposed to make the residual value of the leased property a required disclosure in closed-end leases. (A disclosure called the ''estimated value of the vehicle at the end of the lease'' was already required by Regulation M in an open-end lease.)

Many commenters, including both industry and consumer representatives, favored the disclosure of this term. The residual value is the amount estimated or assigned at consummation as the value of the lease property at the end of the lease term. In motor vehicle leases, this figure is frequently but not always obtained by reference to accepted guides used by lessors, such as the ''ALG Residual Percentage Guide.'' In the payment calculation, the residual value is accompanied by the statement: ''the value of the vehicle at the end of the lease used in calculating your base [periodic] payment.''

4(f)(5) *Depreciation and any amortized amounts.*

The disclosure of the ''depreciation and any amortized amounts'' was not included in the Board's proposed rule but is a necessary part of the payment calculation. The depreciation represents the difference between the adjusted capitalized cost and the residual value. This is the amount that the lessee pays for the vehicle's decline in value attributable to normal use and for other items paid over the lease term.

4(f)(6) *Rent charge.*

This figure, added in the final rule in response to comments, represents the lessor's ''rent'' or ''interest.'' The rent charge is an essential component in the payment calculation.

4(f) (7)–(10) *Total of base periodic payments, lease term, base periodic payment, itemization of other charges, and total periodic payment.*

Several other items are used in the payment calculation. The ''lease term'' and the ''total periodic payment'' are already required disclosures under the CLA, and appear both in the payment calculation and in the payment schedule disclosures. The ''total of base periodic payments'' is not required by the CLA, but was used in open-end lease disclosures and is necessary in the payment calculation. Itemization of the periodic payment (the base monthly payment and other charges that are part of the periodic payment) is also not currently required, although over the years many lessors have routinely provided an itemization. The periodic payment typically consists of an amount for depreciation and a rent charge; there may also be state tax and other fees.

4(g) *Early termination.*

The CLA requires lessors to disclose the conditions under which the lessee or lessor may terminate the lease before the end of the lease term and the amount or method of determining a penalty or other charge for early termination. Lessors typically disclose the method of determining an early termination charge, a disclosure which is often complex.

The proposed rule noted that a U.S. Court of Appeals case, *Lundquist* v. *Security Pacific Automotive Financial Services Corp.*, 993 F.2d 11 (2d Cir.), *cert. denied,* 510 U.S. 959 (1993), caused lessors concern in determining the requirements for disclosing their early termination provisions. In that case, the court held a lessor liable for violating the ''reasonably understandable'' standard for disclosure under Regulation M; the lessor had an early termination formula that the court found to be overly complex and beyond the understanding of the average consumer. Many lessors believe that, given the complexity of modern automobile lease transactions, it is difficult to describe every part of an early termination formula in terms clearly understandable to consumers. In particular, lessors believe that the various methods used to determine the ''unamortized capitalized cost'' portion of their early termination formulas are inherently complex and cannot be reduced to a disclosure that is easily understandable.

In response to the Board's proposal, many commenters (mostly those representing the leasing industry) favored allowing a reference to the name of the method employed to determine the unamortized capitalized cost portion of the early termination formula instead of requiring a detailed description of that method. Opponents believed that merely providing the name of the method would not be useful and would make it difficult or impossible for consumers to compute the amount of an early termination charge. Some consumer advocates believed that in using complex methods and highly complicated descriptions for determining early termination charges, lessors preclude consumers from determining whether the charges themselves are reasonable. (The CLA specifies that charges for early termination must be ''reasonable.'') Other commenters, including some lessors and many consumer representatives, favored a full description of all aspects of a lessor's early termination method, along with an example of how that method would work.

Based on the comments and upon further analysis, the Board continues to believe that the CLA mandates full disclosure of a lessor's method of determining an early termination charge, even if it is complex. Therefore, a full description of the complete early termination method must be disclosed. Given the complexity of the methods involved, however, a lessor is permitted—in giving the full description of its early termination method—to refer by name to a generally accepted method of computing the adjusted lease balance (also known as the unamortized capitalized cost) for purposes of the early termination charge. For example, a lessor may state that the ''constant yield'' method will be utilized in determining the unamortized portion of the gross capitalized cost, but the lessor would have to specify how that figure—and any other term or figure—is used in computing the total early termination charge that would be imposed upon the consumer. Additionally, if a lessor refers to a named method in this manner, the lessor will have to provide a written explanation of that method if requested by the consumer. Lessors should provide clear and understandable explanations of their early termination provisions to consumers. Explanations that are full, accurate, and not intended to be misleading are in compliance with CLA and Regulation M disclosure requirements even if such explanations are complex.

The Board proposed new disclosure requirements in addition to requiring this basic statutory information about charges for terminating a lease early. The proposed rule added a statement alerting consumers about charges for terminating a lease early, and also would have required an example of an early termination charge based on an assumed termination of the lease at the end of the first year. In general, most commenters supported the Board's requiring a general statement warning the consumer of the possibility of substantial charges for early termination.

Many of the commenters representing the leasing industry objected to the Board's proposed requirement of an early termination example. They believed that a transaction-specific example would substantially increase compliance burdens. They said the figure would be difficult to calculate because published residual values at the end of one year are not available; the tables typically start at 24 months. Also, the figure would be imprecise, since charges for early termination are typically determined based on the realized, not the residual, value of the leased property at the time of early termination. The realized value, these commenters pointed out, can vary widely from the residual value based on factors such as the demand for a

particular model and the condition of the vehicle at the time of early termination. Moreover, the example would not be representative of an actual charge because few leases terminate at the end of the first year. It is more typical for termination to occur nearer to the end of the lease.

Industry commenters expressed concern about the compliance burden attached to a transaction-specific mathematical calculation, as well as concern about possible consumer misunderstanding of a numerical example that might be out of line with the amount a consumer would have to pay if, in fact, the lease is terminated early. Some commenters suggested, as an alternative, an enhanced general warning to the effect that charges for early termination could be substantial and ''may be several thousand dollars.'' They also suggested adding a statement that the actual charge will depend on when the lease is terminated, and the earlier the consumer ends the lease, the greater this amount is likely to be.

Commenters representing consumer interests believed that an example is needed to give consumers a concrete idea of just how substantial an early termination charge could be. Some of these commenters suggested that the early termination example could be rephrased to make clear that the early termination charge shown in any example is contingent upon the realized value of the property at the time of termination. They suggested using language such as ''if you terminate this lease at the end of the first year, you may owe the lessor the difference between your adjusted lease balance of [stated amount] and the realized value at that time.''

While there have been very few consumer complaints about consumer leasing at the federal level, one of the more frequent issues raised involves early termination charges. At the state level, authorities report that early terminations are a major source of consumer complaints about leasing. Lessees often are surprised that an early termination charge can be several thousand dollars. Many consumers apparently think that as long as they are current in their monthly payments, upon early termination they can merely return the car owing nothing more or at most a nominal termination fee. The transaction-specific example proposed by the Board was intended to show just how substantial a charge could be. Based on the comments and further analysis, the Board has dropped the requirement of an example and has instead strengthened the warning to consumers. The final rule requires the following revised statement among the segregated disclosures:

Early Termination. You may have to pay a substantial charge if you end this lease early. *The charge may be up to several thousand dollars.* The actual charge will depend on when the lease is terminated. The earlier you end the lease, the greater this charge is likely to be.

The Board believes that a strong narrative statement, even without the proposed example, will serve to apprise consumers that charges for early termination may indeed be quite substantial.

4(h) *Maintenance responsibilities.*

To heighten a consumer's awareness about maintenance responsibilities without imposing substantial compliance costs on lessors, the Board proposed to add a disclosure requirement, among the segregated disclosures, that ''you may be charged for excessive wear and use based on the lessor's standard for normal use.'' Any applicable charge for excessive mileage must also be included. In the final rule, this requirement is limited to motor vehicle leases.

Several commenters requested guidance on disclosing the notice in paragraph 4(h)(3) when a specific figure for excess mileage is not available. They suggested that a description of the method for assessing charges for excess mileage should be allowed in place of a specific amount. The final rule allows a lessor to disclose a description of the method used for calculating excess mileage charges in place of a specific amount, when disclosing an amount is not feasible.

4(i) *Purchase option.*

An association representing automobile lessors sought clarification on whether reference to the fair market value based on an automobile publication such as N.A.D.A. (published by the National Automobile Dealers Association) could be disclosed in place of a sum certain, as the purchase-option price. The Board clarifies that lessors may commit to a sum certain as the purchase-option price at a future date by reference to an independent source. The reference should provide sufficient information so that the lessee will be able to determine the actual price at the time the option becomes available. Statements of a lease end price such as ''negotiated price'' or ''fair market value'' do not comply with the requirement of this paragraph. For a purchase option during the lease term, the Board recognizes that the price may vary depending on when the lessee exercises this option, and therefore under the final rule, lessors are allowed to describe a method for determining the price as an alternative to providing the price.

4(j) *Statement referencing nonsegregated disclosures.*

To alert consumers to the nonsegregated CLA disclosures, the final rule requires a statement among the segregated disclosures to direct consumers to other CLA-required disclosures in the lease documents. The nonsegregated disclosures include information on early termination, purchase options and maintenance responsibilities, warranties, late and default charges, insurance, and any security interest.

4(k) *Liability between residual and realized values.*

This provision is substantially unchanged from the provision found under former § 213.5(g)(13); minor edits have been made.

4(l) *Right of appraisal.*

Paragraph 4(l) requires disclosure of the right to an appraisal of leased property. This language has been adopted as proposed, with a few changes for clarity and accuracy; for example, the term ''realized value'' replaces ''estimated value.'' No substantive change is intended. This provision is applicable both to open-end and to closed-end leases.

4(m) *Liability at end of lease term based on residual value.*

Except as discussed below, editorial changes have been made to this section without substantive change.

4(m)(1) *Rent and other charges.*

Former §§ 213.2(a)(17) and 2(a)(18) defined the terms ''total lease obligation'' and ''value at consummation,'' that were applicable to open-end leases. The Congressional intent regarding these definitions, as set forth in a committee report, was that the lessee would have a readily understandable method for comparing the cost of one lease with another or with the cost of buying the same property for cash or on credit (Senate Committee on Banking, Housing and Urban Affairs, Consumer Leasing Act of 1976, S. Rep. No. 94–590 (1976)). The report stated, in pertinent part:

> Under subsection 182[(10)][of the CLA], in addition the lessor must calculate and disclose the difference between the total lease obligation and the market value of the goods at the inception of the lease. These figures then will provide an easy comparison

between the cost of the lease and the cost of an outright cash purchase, and the differential figure provides a rough comparison to the amount of finance charge which would be involved in a credit purchase. The consumer lessee therefore will have at hand the essential data to compare leases, and to evaluate alternatives to leasing.

Commenters noted that the value at consummation, defined as ''the cost to the lessor of the leased property including, if applicable, any increase or markup by the lessor prior to consummation,'' is essentially the same as the capitalized cost.

The Board believes that the purpose of the disclosure of the total lease obligation, the value at consummation, and the differential between these two figures is served by requiring lessors in open-end leases to disclose the ''rent and other charges'' described as ''the total amount of rent and other charges imposed in connection with your lease [state the amount].'' Because of the new comprehensive disclosure scheme, including a required disclosure of the gross capitalized cost (including the agreed upon value) of leased property, the ''total lease obligation'' disclosure (as defined in former § 213.2(a)(17)), and the ''value at consummation'' disclosure (as defined in former § 213.2(a)(18)) have been deleted as unnecessary. The final rule has been revised accordingly.

4(o) *Insurance.*

Along with the amount paid to the lessor, this disclosure provides information on the type and amount of coverage of insurance, whether voluntary or required, as well as the cost. Several commenters pointed out that unlike collision and comprehensive liability policies, the lessor could not furnish the amount of coverage for mechanical breakdown protection contracts (in states where these contracts are treated as insurance). For mechanical breakdown protection insurance contracts not capped by a dollar amount, lessors may describe coverage by referring to a limitation by mileage or time period. For example, the mechanical breakdown contract insures parts of the automobile for up to 100,000 miles.

4(p) *Warranties or guarantees.*

The Board was asked to clarify whether warranties were limited to maintenance warranties, or included UCC warranties such as warranty of title, and whether disclosure is required if certain warranties do not apply to the lessee. Whether warranties under the UCC should be treated as warranties under this section is to be determined by state or other applicable law. If a lessor provides a comprehensive list of warranties to a consumer, the lessor must indicate which warranties apply or, alternatively, which do not apply.

4(q) Penalties and other charges for delinquency

As proposed, the final rule adds that any penalty or charge shall be reasonable, to reflect the requirement found in § 183(b) of the CLA. No substantive change is intended.

4(r) Security interest

This section has been adopted as proposed without substantive change. The phrase ''in connection with the lease'' has been deleted as unnecessary.

4(s) Limitation on rate information

Until recently, lessors did not disclose rate information to consumers, although they have commonly used an implicit interest rate for internal purposes. Now some automobile lessors disclose rate information in contracts, or advertise lease rates, or orally provide rate information to consumers who lease or express an interest in leasing. Typically these rates are based on the lessor's ''money factor''—representing only the ''rent'' or the ''interest'' charge—and are sometimes labelled as an ''annual percentage rate.''

In the proposed rule, the Board solicited comment on whether Regulation M should require a rate disclosure, and whether (and how) the rate should be made comparable to the annual percentage rate (APR) in a credit transaction. Many commenters addressed this issue. For the most part, commenters representing consumer constituencies advocated the disclosure of a uniformly calculated lease rate. Those representing industry interests generally opposed a lease rate disclosure, although some supported further consideration of the issue.

Those commenters who supported a rate disclosure believed that a federally-mandated annual lease rate is needed to assure uniform disclosure of lease-cost information. They expressed particular concern that rates currently disclosed by some lessors in advertisements and in contracts may mislead consumers about lease costs, given the lack of any calculation standards. Commenters also argued that if the capitalized cost, the residual value of leased property, and other lease terms are disclosed to a consumer, the lease rate is the only missing component necessary to fully demonstrate the cost of the lease. They generally believed that a rate disclosure would be an effective tool for comparison shopping.

Those commenters opposed to a rate disclosure requirement believed that such a disclosure would be meaningless and perhaps even misleading to consumers. They argued that there is no effective way to calculate a lease rate that will be meaningful to consumers, absent rules constraining lease terms. Many expressed concern that consumers would inappropriately compare credit and lease transactions by comparing the APR with the lease rate. A few commenters, mostly representing independent lessors, suggested that the Board would be exceeding its rulemaking authority under the CLA if it were to mandate a rate disclosure, given that the statute does not impose this requirement. Commenters also suggested that a rate disclosure presents the opportunity for unscrupulous lessors to purposely manipulate the lease rate (to make it look more attractive) by adjusting the residual value. These commenters suggested that, to quote a low lease rate, such lessors might use a residual value lower than the figure the lessor actually expects to realize from the sale of the vehicle at the scheduled termination of the lease. Reducing the residual value increases the portion of the periodic payment attributable to depreciation, thus lowering the amount imputed to the rent charge in each payment. Indeed, for lease transactions in which the adjusted capitalized cost, lease term, and periodic payments remain constant, adjustments in the residual value can produce significantly different lease rates.

Consideration of alternative approaches. The Board considered several approaches to address the lease rate issue: it considered requiring, permitting, or prohibiting a disclosure. In principle, the disclosure of a lease cost expressed as an annual rate, rather than solely as a dollar amount, could have value to consumers in negotiating lease terms and in comparing one lease to another. In practice, however, there are problems associated both with the computation of the lease rate and with what the figure represents.

The major problem with a rate computation is that it is subject to variations in the residual value, whether the variation is narrow or wide and whether it results from unscrupulous manipulation or from legitimate, good-faith differences about estimates of value. As to some of the comparisons that consumers might attempt to make, it is arguable that comparing the costs incurred in leasing and in financing based primarily on rate information may never be totally appropriate because the comparison overlooks legal and

economic distinctions between the two transactions—in a lease the consumer accumulates no equity in the property. Given these limitations, and the fact that the legislative history provides little support for requiring a lease rate disclosure, the Board decided not to mandate a lease rate disclosure.

The Board considered prescribing a method for calculating a rate so that consumers could be assured of uniformity in any rate disclosures they received. The calculation could use an ''actuarial method'' formula similar to that used for the APR under the Board's Regulation Z. This formula would analyze the present value of all advances made to the lessee or on the lessee's behalf against the present value of all payments received by the lessor.

To address rate manipulation, the Board considered placing certain general constraints on the use of the residual value, such as requiring that the residual value used to calculate the rate be the same one on which the periodic payments are based, and requiring also that the residual value be a reasonable approximation of the value of the leased property at the end of the lease term. While this approach would promote more uniformity in rate disclosure than currently exists, it would not make the rates quoted to a consumer completely reliable given the legitimate range of residual values. Alternatively, the Board considered requiring that lessors use the purchase-option price instead of the residual value in calculating a rate when the option price is higher. However, basing a lease rate on a purchase-option price assumes, often incorrectly, that the consumer will purchase the leased property at the end of the lease term. Moreover, because only about 60 percent of leases have an option price, this restraint on possible manipulation would not be available in all instances.

Given the limitations under any of these approaches, the Board believes that in specifying a rate calculation method, it would be endorsing the use of an imperfect tool—one whose accurate use for comparison shopping is questionable in many cases.

As an alternative, the Board considered whether to prohibit the disclosure of lease rates. However, a regulatory prohibition would essentially require a determination by the Board that a rate disclosure is inherently deceptive or misleading to consumers. In light of the wide support for a uniform lease rate disclosure among consumer advocates and others, the Board believes it would be difficult to support such a determination in all cases.

Still, the Board believes that the concerns about variations in lease rates cannot be ignored. These concerns exist whether variations result from a lessor's manipulation of the residual value to show a lower lease rate, or occur despite a lessor's use of different good-faith estimates of the residual value. Accordingly, the final rule imposes constraints on the disclosure of rate information to deter—as much as possible—inappropriate comparisons of leases by consumers based on rate information offered by different lessors, and mistaken comparisons between the distinct transactions of financing and leasing. The final rule requires that where rate information is provided in an advertisement or in lease documents, a notice must accompany the rate disclosure stating that ''this percentage may not measure the overall cost of financing this lease.''

Under the final rule, a lessor advertising or disclosing a lease rate is also precluded from calling the rate an ''annual percentage rate'' or any equivalent term to avoid the inference that the rate is directly comparable to the APR. Moreover, the rate may not be placed among Regulation M's segregated disclosures. The final rule in § 213.7(b)(2) also provides that the disclosure of a lease rate in an advertisement cannot be more prominent than disclosures in the advertisement required by Regulation M, except for the disclosure that must accompany the rate.

The estimated lease charge. In its proposed rule, the Board solicited comment on a new disclosure, called the estimated lease charge, to show the total ''financing'' costs that would be charged to the consumer over the lease term, including ''rent'' or ''interest.'' In name, the proposed figure was similar to the finance charge disclosed in credit transactions subject to the TILA. In concept, however, it was quite different in that it included fees that the consumer would pay in a comparable cash transaction and fees paid to third parties (such as automobile registration fees, insurance premiums, and state taxes). These are items that in the credit context would be excluded from the finance charge in most cases.

Commenters representing consumer interests, who generally supported the proposed ''all-inclusive'' definition of the estimated lease charge, believed that such a disclosure meets the goal of the CLA to provide meaningful and full disclosure to consumers of the ''true'' cost of leasing. They thought it could facilitate shopping among comparable lease transactions, and would not be burdensome for lessors to disclose. A majority of commenters—all representing the leasing industry—either opposed the estimated lease charge disclosure in general or as it was defined in the proposal. They believed that any lease charge should ideally reflect only that portion of each lease payment representing the ''rent'' or ''interest'' charged by the lessor. Also, they believed an all-inclusive lease charge disclosure could mislead consumers to view leasing as more expensive in comparison with financing, when that may not be the case. Most of these commenters believed that if a lease charge were to be disclosed, the rules should at least be more comparable to Regulation Z regarding the type of fees included, based on their concern that consumers might attempt to compare a lease charge to the finance charge in a credit transaction.

Although virtually all costs associated with a lease transaction are itemized and disclosed under the final rule, there could be some value in bringing together in one figure the various interest and noninterest charges that may be split among those due at lease signing, in the periodic payments, and at lease end. The Board considered that a lease charge, redefined to more closely parallel the finance charge disclosed in a credit transaction, could have utility in some instances. For example, it might assist a consumer in comparing the cost of leasing a vehicle offered by different lessors, such as when shopping to lease a particular make and model with the same lease duration. It would not be very useful in comparing the leasing of cars with different values or different lease durations, or in comparing a lease transaction to a credit transaction. For purposes of Regulation M, a lease charge disclosure is related primarily to the calculation of a lease rate (as lessors would need to know what fees to include in the calculation) and to verify compliance with the prescribed formula. Given that there is no federally-mandated lease rate disclosure, there is little need for a lease charge disclosure (in a closed-end lease). Based on the comments and upon further analysis, the final rule does not require the disclosure of a lease charge.

Section 213.5 Renegotiations, extensions, and assumptions.

Section 213.5 is adopted as proposed with some editorial changes. No substantive change is intended. This section contains all the redisclosure rules governing leases that are renegotiated, extended, or assumed, which were generally contained in

former § 213.4(h). Paragraphs have been rearranged and revised for clarity. Rules on assumptions have been moved from the commentary. Section 213.5(d) retains the substance of the exceptions found in the former regulation as well as the exceptions previously located in the commentary for renegotiations, court proceedings, and deferrals under former comments 4(h)-3, 7, and 8, respectively.

Section 213.6 [Reserved]

Section 213.7 Advertising.

Former § 213.5 is redesignated as indicated below:

Former	Final rule
213.5(a)	213.7(a).
	213.7(b) new, incorporating standard in one place.
	213.7(b)(1) new.
	213.7(b)(2) new.
213.5(b)	213.7(c).
213.5(c)	213.7(d).
213.5(d)	213.7(e).
	213.7(f) new.

The final rule contains several substantive additions to the advertising rules as discussed below. Some of the language of existing provisions has been revised for simplicity.

7(b) Clear and conspicuous standard.

In response to commenters' request for guidance on the clear and conspicuous standard for advertisements, the Board clarifies that an advertisement must be understandable and readable. For example, very fine print in a television advertisement or detailed and rapidly stated information in a radio advertisement does not meet the clear and conspicuous requirement if consumers cannot see and read or comprehend all of the information required to be disclosed. Further, in the official commentary, the Board proposed to require that lease disclosures appear on a television screen at a minimum of five seconds to meet the clear and conspicuous standard. Upon further analysis, the Board believes that this ''five second'' rule, which was referred to in a case by the Federal Trade Commission, is inadequate as a test for the clear and conspicuous standard. Therefore, the Board is withdrawing the ''five second'' rule as a standard to be used for television advertisements.

7(b)(1) Amount due at lease signing.

The proposal sought to address misleading advertisements primarily in which a lessor refers to a low or no capitalized cost reduction (downpayment) and, in small print lists other upfront charges such as an acquisition fee, a security deposit, the first monthly lease payment. The Board proposed that a reference in an advertisement to any component of the total amount due at lease signing may not be more prominently displayed than the required disclosure of the total amount of payments due at lease signing.

The majority of commenters supported the proposed requirement, stating that it would minimize deceptive practices and that it provided clarity to the clear and conspicuous standard. However, a number of commenters opposed the adoption of an equal prominence rule. They believed the proposed rule was overbroad, and suggested that the final rule should ensure that the prominence rule is not triggered when the only payment due at lease inception is the first scheduled periodic payment. Several commenters sought further clarification on the clear and conspicuous standard.

The final rule provides an exception to the prominence test for the periodic payment. Stating the amount of any periodic payment will not trigger the prominence rule. The rule is triggered by oral or written references (which includes electronic media such as the Internet) to any other component of the total amount due at lease signing. The Board believes the final rule addresses some of the concerns about lease advertisements without adding significant burden on lessors or interfering with the effective marketing of their products. The final rule does not specify what terms are to be advertised, but only that components of the total amount due at lease signing cannot be emphasized without giving equal prominence to the disclosure of the total amount due itself. Lessors can advertise lease transactions without including any CLA disclosures. Disclosures are only required when certain ''trigger'' terms are included in the advertisement. The CLA requires only disclosure of the total due, not an itemization of its component parts, in advertisements. Such an itemization is provided in the transaction-specific disclosures.

7(b)(2) Advertisement of a lease rate.

As discussed in the supplementary information to § 213.4(s), if a percentage rate is stated in an advertisement, a notice must accompany the rate. The notice must be placed next to the rate without any other intervening language or symbols. For example, a lessor may not state a rate with an asterisk and make the disclosure in a different location in the advertisement or lease document. The notice states that this percentage may not measure the overall cost of financing the lease. In addition, with the exception of the notice required by § 213.4(s), the rate cannot be more prominent than the disclosures in the advertisement required by § 213.4.

7(c) Catalogs and multi-page advertisements.

Section 7(c) is adopted as substantially proposed, with no substantive change from the former rule.

7(d) Advertisement of terms that require additional disclosure.

In paragraph 7(d)(2)(iii), the word ''such'' prior to ''payments under the lease,'' inadvertently omitted in the proposal, is inserted back in the paragraph.

In complying with paragraph 7(d)(2)(iv), lessors are required to provide a sum certain if the purchase option is available at the end of the term. Referring to a source for determining a sum certain in the future complies with this requirement. Statements of a lease-end price such as ''negotiated price'' or ''fair market value'' do not comply with the requirement of this paragraph.

7(e) Alternative disclosures—merchandise tags.

The substance of this section is unchanged from the former provision in § 213.5(d); editorial changes have been made.

7(f) Alternative disclosures—telephone or radio advertisements.

Section 336 of the Riegle Community Development and Regulatory Improvement Act of 1994 (Pub. L. 103–325, 108 Stat. 2160) amends § 184 of the CLA to provide an alternative disclosure scheme for radio lease advertisements. In radio advertisements, lessors are permitted to substitute a reference to a toll-free telephone number or to a print advertisement for the disclosures about the purchase option and the end-of-term liability. When calling an advertised toll-free number, if a consumer obtains a recording that provides several dialing options—such as providing directions to the lessor's place of business—the option allowing the consumer to request lease disclosures should be provided early in the phone message to ensure that disclosure information is not obscured by other information.

In keeping with the purpose of the statutory amendment, the final rule requires language to accompany the telephone number indicating that all required disclosures are available by

calling the toll-free number. Without language such as, ''call 1–800–000–0000 for details about costs and terms,'' consumers are not put on notice that disclosures may be obtained by calling the toll-free number. A specific reference to disclosures in print advertisements is also required.

The Board proposed to extend the alternate disclosure provision to television advertisements. The majority of commenters supported this proposal. They agreed that television has the same time and space constraints as radio and that the alternate disclosure provision allows consumers the opportunity to obtain lease information in a format that can be retained and studied at a convenient time.

The Board also solicited comment on whether constraints similar to those for television and radio advertisements exist for print advertisements. Although some commenters encouraged imposing the same standard for both broadcast and print media, the majority of commenters did not support the application of the alternative disclosure rules to print media. Much of the oral and written disclosure information in a broadcast is difficult for lessors to provide and for consumers to comprehend or retain. The Board believes that lessors have the ability to more efficiently provide the required disclosures in print format. And generally, print advertisements are easier to retain for use by consumers who are shopping for a lease. Therefore, the Board has extended the alternate disclosure provision to television but not to print media.

Appendices

To simplify the regulation, the written information contained in former appendices A and B about the procedures and criteria for preemption and exemption determinations have been removed. Such information is available from the Board upon request. The model forms are in appendix A. The list of federal agencies that enforce the CLA for particular classes of businesses is moved from former appendix D to appendix B. Appendix C incorporates former § 213.1(d).

Appendix A—Model Forms

The model forms illustrate the new segregated disclosure scheme required by § 213.3(a)(2). Instructions have been deleted as unnecessary.

A–1—Model Open-End or Finance Vehicle Lease Disclosures

A–2—Model Closed-End or Net Vehicle Lease Disclosures

A–3—Model Furniture Lease Disclosures

VI. Regulatory Flexibility Analysis

In accordance with section 3(a) of the Regulatory Flexibility Act (5 U.S.C 603), the Board's Office of the Secretary has reviewed the amendments to Regulation M. The text of a detailed analysis appears at the end of this document as appendix I. The changes to Regulation M will require a substantial revision to the disclosure format currently required of lessors. In issuing the final rule, the Board has attempted to minimize the burden of changing to the new disclosure format by requiring, wherever possible, disclosures that can be preprinted. Further, the Board has provided model disclosure forms to facilitate compliance. Section 105 of the Truth in Lending Act provides that a lessor that uses the appropriate model forms published by the Board ''shall be deemed to be in compliance with the disclosure provisions of this title with respect to other than numerical disclosures....'' Thus, using the model forms properly provides lessors with a safe harbor from civil liability. Required disclosures will be the same for large and small lessors, but the Board does not expect that the changes to Regulation M will have a substantial adverse economic impact on a large number of small entities. The automobile leasing industry, at which most of the changes are directed, is highly concentrated in a small number of large firms. Actual preparation of lease documents will typically take place in the offices of numerous automobile dealers, many of which are small entities. However, preparation will take place through computer terminals and computer programs provided by the lessors. Because the new forms are provided through the lessors' computer systems, they will be clearer and easier for dealer personnel to understand. Explanations and necessary training of personnel should actually be enhanced and made easier for dealers.

VII. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Ch. 3506; 5 CFR 1320 Appendix A.1), the Board reviewed the final rule under the authority delegated to the Board by the Office of Management and Budget.

The respondents are individuals or businesses that regularly lease, offer to lease, or arrange for the lease of personal property under a consumer lease. The purpose of the disclosures associated with Regulation M is to ensure that lessees of personal property receive meaningful information that enables them to compare lease terms with other leases and, where appropriate, with credit transactions. Records, required in order to evidence compliance with the regulation, must be retained for twenty-four months. The revisions to the disclosure requirements in this regulation are found in §§ 213.3, 213.4, and 213.7.

Regulation M applies to all types of financial institutions, not just state member banks. Under the Paperwork Reduction Act, however, the Federal Reserve accounts for the paperwork burden associated with Regulation M only for state member banks. Any estimate of paperwork burden for institutions other than state member banks affected by the amendments is provided by the federal agency or agencies that supervise those lessors. The Federal Reserve has found that few state member banks engage in consumer leasing and that while the prevalence of leasing has increased in recent years, it has not increased substantially among state member banks. It also has found that among state member banks that engage in consumer leasing, only a very few advertise consumer leases.

The estimated burden per response for the disclosures is eighteen minutes, three minutes more than the estimate of the burden for the disclosures under the former rule. Under the Board's September 1995 proposal, the estimate was seventeen minutes. The final rule adds two particular items: an itemized mathematical progression of the periodic payment and, if an annual lease rate is included, a statement that the rate may not measure the overall cost of financing the lease. The estimated burden for advertisement disclosures, twenty-five minutes (a decrease of five minutes from the former rule), is unchanged since the proposal. It is estimated that there will be 310 respondents and an average frequency of 120 responses per respondent each year. The combined amount of annual burden is estimated to increase from 9,322 hours to 11,179 hours. In addition, start-up costs are estimated to be $12,000 per respondent, amounting to a total of $3,720,000 for state member banks.

The Board received no comments that specifically addressed the burden estimate.

The disclosures made by lessors to consumers under Regulation M are mandatory (15 USC 1667 et seq.). Because the Federal Reserve does not collect any information, no issue of confidentiality under the Freedom of Information Act arises. Consumer lease information in advertisements is available to the public. Disclosures of the costs, liabilities, and terms of

consumer lease transactions relating to specific leases are not publicly available.

An agency may not conduct or sponsor, and an organization or individual is not required to respond to, an information collection unless it displays a currently valid OMB control number. The OMB control number for Regulation M is 7100–0202.

Comments regarding the burden estimate, or any other aspect of this collection of information, including suggestions for reducing the burden, may be sent to: Secretary, Board of Governors of the Federal Reserve System, 20th and C Streets, N.W., Washington, DC 20551; and to the Office of Management and Budget, Paperwork Reduction Project (7100–0202), Washington, DC 20503.

List of Subjects in 12 CFR Part 213

Advertising, Federal Reserve System, Reporting and recordkeeping requirements, Truth in Lending.

For the reasons set forth in the preamble, the Board amends 12 CFR Part 213 as follows:

PART 213—CONSUMER LEASING (REGULATION M)

1. The authority citation for part 213 continues to read as follows:

Authority: 15 U.S.C. 1604.

2. The table of contents to part 213 is revised to read as follows:

Sec.
213.1 Authority, scope, purpose, and enforcement.
213.2 Definitions.
213.3 General disclosure requirements.
213.4 Content of disclosures.
213.5 Renegotiations, extensions, and assumptions.
213.6 [Reserved]
213.7 Advertising.
213.8 Record retention.
213.9 Relation to state laws.
Appendix A to Part 213—Model Forms
Appendix B to Part 213—Federal Enforcement Agencies
Appendix C to Part 213—Issuance of Staff Interpretations
Supplement I to Part 213—Official Staff Commentary to Regulation M

3. Part 213 is amended as follows:

a. Sections 213.1 through 213.5 are revised;

b. Section 213.6 is removed and reserved;

c. Sections 213.7 and 213.8 are revised;

d. Section 213.9 is added;

e. Appendices A through C are revised; and

f. Appendix D is removed.

The revisions and additions read as follows:

§ 213.1 Authority, scope, purpose, and enforcement.

(a) *Authority.* The regulation in this part, known as Regulation M, is issued by the Board of Governors of the Federal Reserve System to implement the consumer leasing provisions of the Truth in Lending Act, which is Title I of the Consumer Credit Protection Act, as amended (15 U.S.C. 1601 et seq.).

(b) *Scope and purpose.* This part applies to all persons that are lessors of personal property under consumer leases as those terms are defined in § 213.2(e)(1) and (h). The purpose of this part is:

(1) To ensure that lessees of personal property receive meaningful disclosures that enable them to compare lease terms with other leases and, where appropriate, with credit transactions;

(2) To limit the amount of balloon payments in consumer lease transactions; and

(3) To provide for the accurate disclosure of lease terms in advertising.

(c) *Enforcement and liability.* Section 108 of the act contains the administrative enforcement provisions. Sections 112, 130, 131, and 185 of the act contain the liability provisions for failing to comply with the requirements of the act and this part.

§ 213.2 Definitions.

For the purposes of this part the following definitions apply:

(a) *Act* means the Truth in Lending Act (15 U.S.C. 1601 et seq.) and the Consumer Leasing Act is chapter 5 of the Truth in Lending Act.

(b) *Advertisement* means a commercial message in any medium that directly or indirectly promotes a consumer lease transaction.

(c) *Board* refers to the Board of Governors of the Federal Reserve System.

(d) *Closed-end lease* means a consumer lease other than an open-end lease as defined in this section.

(e)(1) *Consumer lease* means a contract in the form of a bailment or lease for the use of personal property by a natural person primarily for personal, family, or household purposes, for a period exceeding four months and for a total contractual obligation not exceeding $25,000, whether or not the lessee has the option to purchase or otherwise become the owner of the property at the expiration of the lease. Unless the context indicates otherwise, in this part ''lease'' means ''consumer lease.''

(2) The term does not include a lease that meets the definition of a credit sale in Regulation Z (12 CFR 226.2(a)). It also does not include a lease for agricultural, business, or commercial purposes or a lease made to an organization.

(3) This part does not apply to a lease transaction of personal property which is incident to the lease of real property and which provides that:

(i) The lessee has no liability for the value of the personal property at the end of the lease term except for abnormal wear and tear; and

(ii) The lessee has no option to purchase the leased property.

(f) *Gross capitalized cost* means the amount agreed upon by the lessor and the lessee as the value of the leased property and any items that are capitalized or amortized during the lease term, including but not limited to taxes, insurance, service agreements, and any outstanding balance from a prior loan or lease. *Capitalized cost reduction* means the total amount of any rebate, cash payment, net trade-in allowance, and noncash credit that reduces the gross capitalized cost. The *adjusted capitalized cost* equals the gross capitalized cost less the capitalized cost reduction, and is the amount used by the lessor in calculating the base periodic payment.

(g) *Lessee* means a natural person who enters into or is offered a consumer lease.

(h) *Lessor* means a person who regularly leases, offers to lease, or arranges for the lease of personal property under a consumer lease. A person who has leased, offered, or arranged to lease personal property more than five times in the preceding calendar year or more than five times in the current calendar year is subject to the act and this part.

(i) *Open-end lease* means a consumer lease in which the lessee's liability at the end of the lease term is based on the difference between the residual value of the leased property and its realized value.

(j) *Organization* means a corporation, trust, estate, partnership, cooperative, association, or government entity or instrumentality.

(k) *Person* means a natural person or an organization.

(l) *Personal property* means any property that is not real property under the law of the state where the property is located at the time it is offered or made available for lease.

(m) *Realized value* means:

(1) The price received by the lessor for the leased property at disposition;

(2) The highest offer for disposition of the leased property; or

(3) The fair market value of the leased property at the end of the lease term.

(n) *Residual value* means the value of the leased property at the end of the

lease term, as estimated or assigned at consummation by the lessor, used in calculating the base periodic payment.

(o) *Security interest* and *security* mean any interest in property that secures the payment or performance of an obligation.

(p) *State* means any state, the District of Columbia, the Commonwealth of Puerto Rico, and any territory or possession of the United States.

§ 213.3 General disclosure requirements.

(a) *General requirements.* A lessor shall make the disclosures required by § 213.4, as applicable. The disclosures shall be made clearly and conspicuously in writing in a form the consumer may keep, in accordance with this section.

(1) *Form of disclosures.* The disclosures required by § 213.4 shall be given to the lessee together in a dated statement that identifies the lessor and the lessee; the disclosures may be made either in a separate statement that identifies the consumer lease transaction or in the contract or other document evidencing the lease. Alternatively, the disclosures required to be segregated from other information under paragraph (a)(2) of this section may be provided in a separate dated statement that identifies the lease, and the other required disclosures may be provided in the lease contract or other document evidencing the lease. In a lease of multiple items, the property description required by § 213.4(a) may be given in a separate statement that is incorporated by reference in the disclosure statement required by this paragraph.

(2) *Segregation of certain disclosures.* The following disclosures shall be segregated from other information and shall contain only directly related information: §§ 213.4(b) through (f), (g)(2), (h)(3), (i)(1), (j), and (m)(1). The headings, content, and format for the disclosures referred to in this paragraph (a)(2) shall be provided in a manner substantially similar to the applicable model form in appendix A of this part.

(3) *Timing of disclosures.* A lessor shall provide the disclosures to the lessee prior to the consummation of a consumer lease.

(4) *Language of disclosures.* The disclosures required by § 213.4 may be made in a language other than English provided that they are made available in English upon the lessee's request.

(b) *Additional information; nonsegregated disclosures.* Additional information may be provided with any disclosure not listed in paragraph (a)(2) of this section, but it shall not be stated, used, or placed so as to mislead or confuse the lessee or contradict, obscure, or detract attention from any disclosure required by this part.

(c) *Multiple lessors or lessees.* When a transaction involves more than one lessor, the disclosures required by this part may be made by one lessor on behalf of all the lessors. When a lease involves more than one lessee, the lessor may provide the disclosures to any lessee who is primarily liable on the lease.

(d) *Use of estimates.* If an amount or other item needed to comply with a required disclosure is unknown or unavailable after reasonable efforts have been made to ascertain the information, the lessor may use a reasonable estimate that is based on the best information available to the lessor, is clearly identified as an estimate, and is not used to circumvent or evade any disclosures required by this part.

(e) *Effect of subsequent occurrence.* If a required disclosure becomes inaccurate because of an event occurring after consummation, the inaccuracy is not a violation of this part.

(f) *Minor variations.* A lessor may disregard the effects of the following in making disclosures:

(1) That payments must be collected in whole cents;

(2) That dates of scheduled payments may be different because a scheduled date is not a business day;

(3) That months have different numbers of days; and

(4) That February 29 occurs in a leap year.

§ 213.4 Content of disclosures.

For any consumer lease subject to this part, the lessor shall disclose the following information, as applicable:

(a) *Description of property.* A brief description of the leased property sufficient to identify the property to the lessee and lessor.

(b) *Amount due at lease signing.* The total amount to be paid prior to or at consummation, using the term ''amount due at lease signing.'' The lessor shall itemize each component by type and amount, including any refundable security deposit, advance monthly or other periodic payment, and capitalized cost reduction; and in motor-vehicle leases, shall itemize how the amount due will be paid, by type and amount, including any net trade-in allowance, rebates, noncash credits, and cash payments in a format substantially similar to the model forms in appendix A of this part.

(c) *Payment schedule and total amount of periodic payments.* The number, amount, and due dates or periods of payments scheduled under the lease, and the total amount of the periodic payments.

(d) *Other charges.* The total amount of other charges payable to the lessor, itemized by type and amount, that are not included in the periodic payments. Such charges include the amount of any liability the lease imposes upon the lessee at the end of the lease term; the potential difference between the residual and realized values referred to in paragraph (k) of this section is excluded.

(e) *Total of payments.* The total of payments, with a description such as ''the amount you will have paid by the end of the lease.'' This amount is the sum of the amount due at lease signing (less any refundable amounts), the total amount of periodic payments (less any portion of the periodic payment paid at lease signing), and other charges under paragraphs (b), (c), and (d) of this section. In an open-end lease, a description such as ''you will owe an additional amount if the actual value of the vehicle is less than the residual value'' shall accompany the disclosure.

(f) *Payment calculation.* In a motor-vehicle lease, a mathematical progression of how the scheduled periodic payment is derived, in a format substantially similar to the applicable model form in appendix A of this part, which shall contain the following:

(1) *Gross capitalized cost.* The gross capitalized cost, including a disclosure of the agreed upon value of the vehicle, a description such as ''the agreed upon value of the vehicle [state the amount] and any items you pay for over the lease term (such as service contracts, insurance, and any outstanding prior loan or lease balance),'' and a statement of the lessee's option to receive a separate written itemization of the gross capitalized cost. If requested by the lessee, the itemization shall be provided before consummation.

(2) *Capitalized cost reduction.* The capitalized cost reduction, with a description such as ''the amount of any net trade-in allowance, rebate, noncash credit, or cash you pay that reduces the gross capitalized cost.''

(3) *Adjusted capitalized cost.* The adjusted capitalized cost, with a description such as ''the amount used in calculating your base [periodic] payment.''

(4) *Residual value.* The residual value, with a description such as ''the value of the vehicle at the end of the lease used in calculating your base [periodic] payment.''

(5) *Depreciation and any amortized amounts.* The depreciation and any amortized amounts, which is the difference between the adjusted

capitalized cost and the residual value, with a description such as ''the amount charged for the vehicle's decline in value through normal use and for any other items paid over the lease term.''

(6) *Rent charge.* The rent charge, with a description such as ''the amount charged in addition to the depreciation and any amortized amounts.'' This amount is the difference between the total of the base periodic payments over the lease term minus the depreciation and any amortized amounts.

(7) *Total of base periodic payments.* The total of base periodic payments with a description such as ''depreciation and any amortized amounts plus the rent charge.''

(8) *Lease term.* The lease term with a description such as ''the number of [periods of repayment] in your lease.''

(9) *Base periodic payment.* The total of the base periodic payments divided by the number of payment periods in the lease.

(10) *Itemization of other charges.* An itemization of any other charges that are part of the periodic payment.

(11) *Total periodic payment.* The sum of the base periodic payment and any other charges that are part of the periodic payment.

(g) *Early termination*—(1) *Conditions and disclosure of charges.* A statement of the conditions under which the lessee or lessor may terminate the lease prior to the end of the lease term; and the amount or a description of the method for determining the amount of any penalty or other charge for early termination, which must be reasonable.

(2) *Early-termination notice.* In a motor-vehicle lease, a notice substantially similar to the following: ''Early Termination. You may have to pay a substantial charge if you end this lease early. *The charge may be up to several thousand dollars.* The actual charge will depend on when the lease is terminated. The earlier you end the lease, the greater this charge is likely to be.''

(h) *Maintenance responsibilities.* The following provisions are required:

(1) *Statement of responsibilities.* A statement specifying whether the lessor or the lessee is responsible for maintaining or servicing the leased property, together with a brief description of the responsibility;

(2) *Wear and use standard.* A statement of the lessor's standards for wear and use (if any), which must be reasonable; and

(3) *Notice of wear and use standard.* In a motor-vehicle lease, a notice regarding wear and use substantially similar to the following: ''Excessive Wear and Use. You may be charged for excessive wear based on our standards for normal use.'' The notice shall also specify the amount or method for determining any charge for excess mileage.

(i) *Purchase option.* A statement of whether or not the lessee has the option to purchase the leased property, and:

(1) *End of lease term.* If at the end of the lease term, the purchase price; and

(2) *During lease term.* If prior to the end of the lease term, the purchase price or the method for determining the price and when the lessee may exercise this option.

(j) *Statement referencing nonsegregated disclosures.* A statement that the lessee should refer to the lease documents for additional information on early termination, purchase options and maintenance responsibilities, warranties, late and default charges, insurance, and any security interests, if applicable.

(k) *Liability between residual and realized values.* A statement of the lessee's liability, if any, at early termination or at the end of the lease term for the difference between the residual value of the leased property and its realized value.

(l) *Right of appraisal.* If the lessee's liability at early termination or at the end of the lease term is based on the realized value of the leased property, a statement that the lessee may obtain, at the lessee's expense, a professional appraisal by an independent third party (agreed to by the lessee and the lessor) of the value that could be realized at sale of the leased property. The appraisal shall be final and binding on the parties.

(m) *Liability at end of lease term based on residual value.* If the lessee is liable at the end of the lease term for the difference between the residual value of the leased property and its realized value:

(1) *Rent and other charges.* The rent and other charges, paid by the lessee and required by the lessor as an incident to the lease transaction, with a description such as ''the total amount of rent and other charges imposed in connection with your lease [state the amount].''

(2) *Excess liability.* A statement about a rebuttable presumption that, at the end of the lease term, the residual value of the leased property is unreasonable and not in good faith to the extent that the residual value exceeds the realized value by more than three times the base monthly payment (or more than three times the average payment allocable to a monthly period, if the lease calls for periodic payments other than monthly); and that the lessor cannot collect the excess amount unless the lessor brings a successful court action and pays the lessee's reasonable attorney's fees, or unless the excess of the residual value over the realized value is due to unreasonable or excessive wear or use of the leased property (in which case the rebuttable presumption does not apply).

(3) *Mutually agreeable final adjustment.* A statement that the lessee and lessor are permitted, after termination of the lease, to make any mutually agreeable final adjustment regarding excess liability.

(n) *Fees and taxes.* The total dollar amount for all official and license fees, registration, title, or taxes required to be paid to the lessor in connection with the lease.

(o) *Insurance.* A brief identification of insurance in connection with the lease including:

(1) *Voluntary insurance.* If the insurance is provided by or paid through the lessor, the types and amounts of coverage and the cost to the lessee; or

(2) *Required insurance.* If the lessee must obtain the insurance, the types and amounts of coverage required of the lessee.

(p) *Warranties or guarantees.* A statement identifying all express warranties and guarantees from the manufacturer or lessor with respect to the leased property that apply to the lessee.

(q) *Penalties and other charges for delinquency.* The amount or the method of determining the amount of any penalty or other charge for delinquency, default, or late payments, which must be reasonable.

(r) *Security interest.* A description of any security interest, other than a security deposit disclosed under paragraph (b) of this section, held or to be retained by the lessor; and a clear identification of the property to which the security interest relates.

(s) *Limitations on rate information.* If a lessor provides a percentage rate in an advertisement or in documents evidencing the lease transaction, a notice stating that ''this percentage may not measure the overall cost of financing this lease'' shall accompany the rate disclosure. The lessor shall not use the term ''annual percentage rate,'' ''annual lease rate,'' or any equivalent term.

§ 213.5 Renegotiations, extensions, and assumptions.

(a) *Renegotiation.* A renegotiation occurs when a consumer lease subject to this part is satisfied and replaced by a new lease undertaken by the same consumer. A renegotiation requires new

disclosures, except as provided in paragraph (d) of this section.

(b) *Extension.* An extension is a continuation, agreed to by the lessor and the lessee, of an existing consumer lease beyond the originally scheduled end of the lease term, except when the continuation is the result of a renegotiation. An extension that exceeds six months requires new disclosures, except as provided in paragraph (d) of this section.

(c) *Assumption.* New disclosures are not required when a consumer lease is assumed by another person, whether or not the lessor charges an assumption fee.

(d) *Exceptions.* New disclosures are not required for the following, even if they meet the definition of a renegotiation or an extension:

(1) A reduction in the lease charge;

(2) The deferment of one or more payments, whether or not a fee is charged;

(3) The extension of a lease for not more than six months on a month-to-month basis or otherwise;

(4) A substitution of leased property with property that has a substantially equivalent or greater economic value, provided no other lease terms are changed;

(5) The addition, deletion, or substitution of leased property in a multiple-item lease, provided the average periodic payment does not change by more than 25 percent; or

(6) An agreement resulting from a court proceeding.

§ 213.6 [Reserved]

§ 213.7 Advertising.

(a) *General rule.* An advertisement for a consumer lease may state that a specific lease of property at specific amounts or terms is available only if the lessor usually and customarily leases or will lease the property at those amounts or terms.

(b) *Clear and conspicuous standard.* Disclosures required by this section shall be made clearly and conspicuously.

(1) *Amount due at lease signing.* Except for the statement of a periodic payment, any affirmative or negative reference to a charge that is a part of the total amount due at lease signing under paragraph (d)(2)(ii) of this section, such as the amount of any capitalized cost reduction (or no capitalized cost reduction is required), shall not be more prominent than the disclosure of the total amount due at lease signing.

(2) *Advertisement of a lease rate.* If a lessor provides a percentage rate in an advertisement, the rate shall not be more prominent than any of the disclosures in § 213.4, with the exception of the notice in § 213.4(s) required to accompany the rate; and the lessor shall not use the term ''annual percentage rate,'' ''annual lease rate,'' or equivalent term.

(c) *Catalogs and multipage advertisements.* A catalog or other multipage advertisement that provides a table or schedule of the required disclosures shall be considered a single advertisement if, for lease terms that appear without all the required disclosures, the advertisement refers to the page or pages on which the table or schedule appears.

(d) *Advertisement of terms that require additional disclosure.*—(1) *Triggering terms.* An advertisement that states any of the following items shall contain the disclosures required by paragraph (d)(2) of this section, except as provided in paragraphs (e) and (f) of this section:

(i) The amount of any payment;

(ii) The number of required payments; or

(iii) A statement of any capitalized cost reduction or other payment required prior to or at consummation, or that no payment is required.

(2) *Additional terms.* An advertisement stating any item listed in paragraph (d)(1) of this section shall also state the following items:

(i) That the transaction advertised is a lease;

(ii) The total amount due at lease signing, or that no payment is required;

(iii) The number, amounts, due dates or periods of scheduled payments, and total of such payments under the lease;

(iv) A statement of whether or not the lessee has the option to purchase the leased property, and where the lessee has the option to purchase at the end of the lease term, the purchase-option price. The method of determining the purchase-option price may be substituted in disclosing the lessee's option to purchase the leased property prior to the end of the lease term;

(v) A statement of the amount, or the method for determining the amount, of the lessee's liability (if any) at the end of the lease term; and

(vi) A statement of the lessee's liability (if any) for the difference between the residual value of the leased property and its realized value at the end of the lease term.

(e) *Alternative disclosures—merchandise tags.* A merchandise tag stating any item listed in paragraph (d)(1) of this section may comply with paragraph (d)(2) of this section by referring to a sign or display prominently posted in the lessor's place of business that contains a table or schedule of the required disclosures.

(f) *Alternative disclosures—television or radio advertisements.*—(1) *Toll-free number or print advertisement.* An advertisement made through television or radio stating any item listed in paragraph (d)(1) of this section complies with paragraph (d)(2) of this section if the advertisement states the items listed in paragraphs (d)(2)(i) through (iii) of this section, and:

(i) Lists a toll-free telephone number along with a reference that such number may be used by consumers to obtain the information required by paragraph (d)(2) of this section; or

(ii) Directs the consumer to a written advertisement in a publication of general circulation in the community served by the media station, including the name and the date of the publication, with a statement that information required by paragraph (d)(2) of this section is included in the advertisement. The written advertisement shall be published beginning at least three days before and ending at least ten days after the broadcast.

(2) *Establishment of toll-free number.* (i) The toll-free telephone number shall be available for no fewer than ten days, beginning on the date of the broadcast.

(ii) The lessor shall provide the information required by paragraph (d)(2) of this section orally, or in writing upon request.

§ 213.8 Record retention.

A lessor shall retain evidence of compliance with the requirements imposed by this part, other than the advertising requirements under § 213.7, for a period of not less than two years after the date the disclosures are required to be made or an action is required to be taken.

§ 213.9 Relation to state laws.

(a) *Inconsistent state law.* A state law that is inconsistent with the requirements of the act and this part is preempted to the extent of the inconsistency. If a lessor cannot comply with a state law without violating a provision of this part, the state law is inconsistent within the meaning of section 186(a) of the act and is preempted, unless the state law gives greater protection and benefit to the consumer. A state, through an official having primary enforcement or interpretative responsibilities for the state consumer leasing law, may apply to the Board for a preemption determination.

(b) *Exemptions.*—(1) *Application.* A state may apply to the Board for an

exemption from the requirements of the act and this part for any class of lease transactions within the state. The Board will grant such an exemption if the Board determines that:

(i) The class of leasing transactions is subject to state law requirements substantially similar to the act and this part or that lessees are afforded greater protection under state law; and

(ii) There is adequate provision for state enforcement.

(2) *Enforcement and liability.* After an exemption has been granted, the requirements of the applicable state law (except for additional requirements not imposed by federal law) will constitute the requirements of the act and this part. No exemption will extend to the civil liability provisions of sections 130, 131, and 185 of the act.

Appendix A to Part 213—Model Forms

A–1 Model Open-End or Finance Vehicle Lease Disclosures

A–2 Model Closed-End or Net Vehicle Lease Disclosures

A–3 Model Furniture Lease Disclosures

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Appendix A-1 Model Open-End or Finance Vehicle Lease Disclosures

Federal Consumer Leasing Act Disclosures

Date _____

Lessor(s) _____ **Lessee(s)** _____

Amount Due at Lease Signing	**Monthly Payments**	**Other Charges** (not part of your monthly payment)	**Total of Payments** (The amount you will have paid by the end of the lease)
(Itemized below)* $ _____	Your first monthly payment of $ _____ is due on _____, followed by _____ payments of $ _____ due on the _____ of each month. The total of your monthly payments is $ _____.	Disposition fee (if you do not purchase the vehicle) $ _____ [Annual tax] _____ _____ _____ Total $ _____	$ _____ You will owe an additional amount if the actual value of the vehicle is less than the residual value.

*** Itemization of Amount Due at Lease Signing**

Amount Due At Lease Signing:

Capitalized cost reduction	$ _____
First monthly payment	_____
Refundable security deposit	_____
Title fees	_____
Registration fees	_____
_____	_____
Total	$ _____

How the Amount Due at Lease Signing will be paid:

Net trade-in allowance	$ _____
Rebates and noncash credits	_____
Amount to be paid in cash	_____
Total	$ _____

Your monthly payment is determined as shown below:

Gross capitalized cost. The agreed upon value of the vehicle ($ _____) and any items you pay over the lease term (such as service contracts, insurance, and any outstanding prior loan or lease balance) ..... $ _____

If you want an itemization of this amount, please check this box. ☐

Capitalized cost reduction. The amount of any net trade-in allowance, rebate, noncash credit, or cash you pay that reduces the gross capitalized cost ..... − _____

Adjusted capitalized cost. The amount used in calculating your base monthly payment ..... = _____

Residual value. The value of the vehicle at the end of the lease used in calculating your base monthly payment ..... − _____

Depreciation and any amortized amounts. The amount charged for the vehicle's decline in value through normal use and for other items paid over the lease term ..... = _____

Rent charge. The amount charged in addition to the depreciation and any amortized amounts ..... + _____

Total of base monthly payments. The depreciation and any amortized amounts plus the rent charge ..... = _____

Lease term. The number of months in your lease ..... ÷ _____

Base monthly payment ..... = _____

Monthly sales/use tax ..... + _____

_____ ..... + _____

Total monthly payment ..... =$ _____

Rent and other charges. The total amount of rent and other charges imposed in connection with your lease $ _____ .

Early Termination. You may have to pay a substantial charge if you end this lease early. The charge may be up to several thousand dollars. The actual charge will depend on when the lease is terminated. The earlier you end the lease, the greater this charge is likely to be.

Excessive Wear and Use. You may be charged for excessive wear based on our standards for normal use [and for mileage in excess of _____ miles per year at the rate of _____ per mile].

Purchase Option at End of Lease Term. [You have an option to purchase the vehicle at the end of the lease term for $ _____ [and a purchase option fee of $ _____].] [You do not have an option to purchase the vehicle at the end of the lease term.]

Other Important Terms. See your lease documents for additional information on early termination, purchase options and maintenance responsibilities, warranties, late and default charges, insurance, and any security interest, if applicable.

[The following provisions are the nonsegregated disclosures required under Regulation M.]

Official Fees and Taxes. The total amount you will pay for official and license fees, registration, title, and taxes over the term of your lease, whether included with your monthly payments or assessed otherwise: $_____ .

Insurance. The following types and amounts of insurance will be acquired in connection with this lease:

_____ .

_____ We (lessor) will provide the insurance coverage quoted above for a total premium cost of $_____.

_____ You (lessee) agree to provide insurance coverage in the amount and types indicated above.

End of Term Liability. (a) The residual value ($ _____) of the vehicle is based on a reasonable, good faith estimate of the value of the vehicle at the end of the lease term. If the actual value of the vehicle at that time is greater than the residual value, you will have no further liability under this lease, except for other charges already incurred [and are entitled to a credit or refund of any surplus.] If the actual value of the vehicle is less than the residual value, you will be liable for any difference up to $ _____ (3 times the monthly payment). For any difference in excess of that amount, you will be liable only if:
1. Excessive use or damage [as described in paragraph ____] [representing more than normal wear and use] resulted in an unusually low value at the end of the term.
2. The matter is not otherwise resolved and we win a lawsuit against you seeking a higher payment.
3. You voluntarily agree with us after the end of the lease term to make a higher payment.
Should we bring a lawsuit against you, we must prove that our original estimate of the value of the leased property at the end of the lease term was reasonable and was made in good faith. For example, we might prove that the actual was less than the original estimated value, although the original estimate was reasonable, because of an unanticipated decline in value for that type of vehicle. We must also pay your attorney's fees.
(b) If you disagree with the value we assign to the vehicle, you may obtain, at your own expense, from an independent third party agreeable to both of us, a professional appraisal of the _____ value of the leased vehicle which could be realized at sale. The appraised value shall then be used as the actual value.

Standards for Wear and Use. The following standards are applicable for determining unreasonable or excess wear and use of the leased vehicle:

_____ .

Maintenance.
[You are responsible for the following maintenance and servicing of the leased vehicle:

_____].

[We are responsible for the following maintenance and servicing of the leased vehicle:

_____].

Warranties. The leased vehicle is subject to the following express warranties:

_____ .

Early Termination and Default. (a) You may terminate this lease before the end of the lease term under the following conditions:

_____ .

The charge for such early termination is:

_____ .

(b) We may terminate this lease before the end of the lease term under the following conditions:

_____ .

Upon such termination we shall be entitled to the following charge(s) for:

_____ .

(c) To the extent these charges take into account the value of the vehicle at termination, if you disagree with the value we assign to the vehicle, you may obtain, at your own expense, from an independent third party agreeable to both of us, a professional appraisal of the _____ value of the leased vehicle which could be realized at sale. The appraised value shall then be used as the actual value.

Security Interest. We reserve a security interest of the following type in the property listed below to secure performance of your obligations under this lease:

_____ .

Late Payments. The charge for late payments is: _____ .

Option to Purchase Leased Property Prior to the End of the Lease. [You have an option to purchase the leased vehicle prior to the end of the term. The price will be [$ _____ /[the method of determining the price].] [You do not have an option to purchase the leased vehicle.]

Appendix A-2 Model Closed-End or Net Vehicle Lease Disclosures

Federal Consumer Leasing Act Disclosures

Date _____

Lessor(s) _____ **Lessee(s)** _____

Amount Due at Lease Signing	**Monthly Payments**	**Other Charges** (not part of your monthly payment)	**Total of Payments** (The amount you will have paid by the end of the lease)
(Itemized below)* $ _____	Your first monthly payment of $ _____ is due on _____, followed by _____ payments of $ _____ due on the _____ of each month. The total of your monthly payments is $ _____.	Disposition fee (if you do not purchase the vehicle) $_____ [Annual tax] _____ _____ _____ Total $_____	$ _____

*** Itemization of Amount Due at Lease Signing**

Amount Due At Lease Signing:

Capitalized cost reduction	$ _____
First monthly payment	_____
Refundable security deposit	_____
Title fees	_____
Registration fees	_____
_____	_____
Total	$ _____

How the Amount Due at Lease Signing will be paid:

Net trade-in allowance	$ _____
Rebates and noncash credits	_____
Amount to be paid in cash	_____
Total	$ _____

Your monthly payment is determined as shown below:

Gross capitalized cost. The agreed upon value of the vehicle ($_____) and any items you pay over the lease term (such as service contracts, insurance, and any outstanding prior loan or lease balance) ..... $ _____

If you want an itemization of this amount, please check this box. ☐

Capitalized cost reduction. The amount of any net trade-in allowance, rebate, noncash credit, or cash you pay that reduces the gross capitalized cost ..... − _____

Adjusted capitalized cost. The amount used in calculating your base monthly payment ..... = _____

Residual value. The value of the vehicle at the end of the lease used in calculating your base monthly payment ..... − _____

Depreciation and any amortized amounts. The amount charged for the vehicle's decline in value through normal use and for other items paid over the lease term ..... = _____

Rent charge. The amount charged in addition to the depreciation and any amortized amounts ..... + _____

Total of base monthly payments. The depreciation and any amortized amounts plus the rent charge ..... = _____

Lease term. The number of months in your lease ..... ÷ _____

Base monthly payment ..... = _____

Monthly sales/use tax ..... + _____

_____ ..... + _____

Total monthly payment ..... =$ _____

Early Termination. You may have to pay a substantial charge if you end this lease early. The charge may be up to several thousand dollars. The actual charge will depend on when the lease is terminated. The earlier you end the lease, the greater this charge is likely to be.

Excessive Wear and Use. You may be charged for excessive wear based on our standards for normal use [and for mileage in excess of _____ miles per year at the rate of _____ per mile].

Purchase Option at End of Lease Term. [You have an option to purchase the vehicle at the end of the lease term for $ _____ [and a purchase option fee of $ _____].] [You do not have an option to purchase the vehicle at the end of the lease term.]

Other Important Terms. See your lease documents for additional information on early termination, purchase options and maintenance responsibilities, warranties, late and default charges, insurance, and any security interest, if applicable.

[The following provisions are the nonsegregated disclosures required under Regulation M.]

Official Fees and Taxes. The total amount you will pay for official and license fees, registration, title, and taxes over the term of your lease, whether included with your monthly payments or assessed otherwise: $_____ .

Insurance. The following types and amounts of insurance will be acquired in connection with this lease:

_____ .

_____ We (lessor) will provide the insurance coverage quoted above for a total premium cost of $_____.

_____ You (lessee) agree to provide insurance coverage in the amount and types indicated above.

Standards for Wear and Use. The following standards are applicable for determining unreasonable or excess wear and use of the leased vehicle:

_____ .

Maintenance.
[You are responsible for the following maintenance and servicing of the leased vehicle:

_____].

[We are responsible for the following maintenance and servicing of the leased vehicle:

_____].

Warranties. The leased vehicle is subject to the following express warranties:

_____ .

Early Termination and Default. (a) You may terminate this lease before the end of the lease term under the following conditions:

_____ .

The charge for such early termination is:

_____ .

(b) We may terminate this lease before the end of the lease term under the following conditions:

_____ .

Upon such termination we shall be entitled to the following charge(s) for:

_____ .

(c) To the extent these charges take into account the value of the vehicle at termination, if you disagree with the value we assign to the vehicle, you may obtain, at your own expense, from an independent third party agreeable to both of us, a professional appraisal of the _____ value of the leased vehicle which could be realized at sale. The appraised value shall then be used as the actual value.

Security Interest. We reserve a security interest of the following type in the property listed below to secure performance of your obligations under this lease:

_____ .

Late Payments. The charge for late payments is: _____ .

Option to Purchase Leased Property Prior to the End of the Lease. [You have an option to purchase the leased vehicle prior to the end of the term. The price will be [$ _____ /[the method of determining the price].] [You do not have an option to purchase the leased vehicle.]

Appendix A-3 Model Furniture Lease Disclosures

Federal Consumer Leasing Act Disclosures

Date _____

Lessor(s) _____ **Lessee(s)** _____

Description of Leased Property				
Item	Color	Stock #	Mfg.	Quantity

Amount Due at Lease Signing	**Monthly Payments**	**Other Charges** (not part of your monthly payment)	**Total of Payments** (The amount you will have paid by the end of the lease)
First monthly payment $ _____ Refundable security deposit $ _____ Delivery/Installation fee $ _____ _____ $ _____ Total $ _____	Your first monthly payment of $ _____ is due on _____, followed by _____ payments of $ _____ due on the _____ of each month. The total of your monthly payments is $ _____.	Pick-up fee $ _____ _____ $ _____ Total $ _____	$ _____

Purchase Option at End of Lease Term. [You have an option to purchase the leased property at the end of the lease term for $ _____ [and a purchase option fee of $ _____].] [You do not have an option to purchase the leased property at the end of the lease term.]

Other Important Terms. See your lease documents for additional information on early termination, purchase options and maintenance responsibilities, warranties, late and default charges, insurance, and any security interest, if applicable.

[The following provisions are the nonsegregated disclosures required under Regulation M.]

Official Fees and Taxes. The total amount you will pay for official fees, and taxes over the term of your lease, whether included with your monthly payments or assessed otherwise: $ _____ .

Insurance. The following types and amounts of insurance will be acquired in connection with this lease: _____
_____ .

_____ We (lessor) will provide the insurance coverage quoted above for a total premium cost of $ _____ .

_____ You (lessee) agree to provide insurance coverage in the amount and types indicated above.

Standards for Wear and Use. The following standards are applicable for determining unreasonable or excess wear and use of the leased property:
_____

Maintenance.

[You are responsible for the following maintenance and servicing of the leased property:
_____.]

[We are responsible for the following maintenance and servicing of the leased property:
_____.]

Warranties. The leased property is subject to the following express warranties:
_____ .

Early Termination and Default. (a) You may terminate this lease before the end of the lease term under the following conditions:
_____ .

The charge for such early termination is: _____ .

(b) We may terminate this lease before the end of the lease term under the following conditions: _____ .

Upon such termination we shall be entitled to the following charge(s) for: _____ .

Early Termination and Default. (continued)

(c) To the extent these charges take into account the value of the leased property at termination, if you disagree with the value we assign to the property, you may obtain, at your own expense, from an independent third party agreeable to both of us, a professional appraisal of the _____ value of the property which could be realized at sale. The appraised value shall then be used as the actual value.

Security Interest. We reserve a security interest of the following type in the property listed below to secure performance of your obligations under this lease: _____.

Late Payments. The charge for late payments is: _____.

Purchase Option Prior to the End of the Lease Term.

[You have an option to purchase the leased property prior to the end of the term. The price will be [$ _____]/the method of determining the price].]

[You do not have an option to purchase the leased property.]

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Appendix B to Part 213—Federal Enforcement Agencies

The following list indicates which federal agency enforces Regulation M (12 CFR Part 213) for particular classes of business. Any questions concerning compliance by a particular business should be directed to the appropriate enforcement agency. Terms that are not defined in the Federal Deposit Insurance Act (12 U.S.C. 1813(s)) shall have the meaning given to them in the International Banking Act of 1978 (12 U.S.C. 3101).

1. *National banks and federal branches and federal agencies of foreign banks*
   District office of the Office of the Comptroller of the Currency for the district in which the institution is located.
2. *State member banks, branches and agencies of foreign banks (other than federal branches, federal agencies, and insured state branches of foreign banks), commercial lending companies owned or controlled by foreign banks, and organizations operating under section 25 or 25A of the Federal Reserve Act*
   Federal Reserve Bank serving the District in which the institution is located.
3. *Nonmember insured banks and insured state branches of foreign banks*
   Federal Deposit Insurance Corporation Regional Director for the region in which the institution is located.
4. *Savings institutions insured under the Savings Association Insurance Fund of the FDIC and federally chartered savings banks insured under the Bank Insurance Fund of the FDIC (but not including state-chartered savings banks insured under the Bank Insurance Fund)*
   Office of Thrift Supervision regional director for the region in which the institution is located.
5. *Federal credit unions*
   Regional office of the National Credit Union Administration serving the area in which the federal credit union is located.
6. *Air carriers*
   Assistant General Counsel for Aviation Enforcement and Proceedings, Department of Transportation, 400 Seventh Street, S.W., Washington, DC 20590
7. *Those subject to Packers and Stockyards Act*
   Nearest Packers and Stockyards Administration area supervisor.
8. *Federal Land Banks, Federal Land Bank Associations, Federal Intermediate Credit Banks, and Production Credit Associations*
   Farm Credit Administration, 490 L'Enfant Plaza, S.W., Washington, DC 20578
9. *All other lessors (lessors operating on a local or regional basis should use the address of the FTC regional office in which they operate)*
   Division of Credit Practices, Bureau of Consumer Protection, Federal Trade Commission, Washington, DC 20580

Appendix C to Part 213—Issuance of Staff Interpretations

Officials in the Board's Division of Consumer and Community Affairs are authorized to issue official staff interpretations of this Regulation M (12 CFR Part 213). These interpretations provide the formal protection afforded under section 130(f) of the act. Except in unusual circumstances, interpretations will not be issued separately but will be incorporated in an official commentary to Regulation M (Supplement I of this part), which will be amended periodically. No staff interpretations will be issued approving lessor's forms, statements, or calculation tools or methods.

Supplement I to Part 213—[Amended]

4. The Supplement to part 213 is amended by revising the heading to read as follows:

Supplement I to Part 213—Official Staff Commentary to Regulation M

Note: Appendix I will not appear in the Code of Federal Regulations.

Appendix I to the Preamble—Regulatory Flexibility Analysis

I. Introduction

Acquiring and financing a substantial asset through purchase credit or a lease contract ranks among the most complicated financial transactions a typical consumer undertakes. In fundamental economic terms, however, a consumer's decision whether to lease rather than use more traditional forms of credit is relatively straightforward. Stating the problem in its simplest form, a consumer should lease an asset rather than purchase it on credit if the discounted present cost of all the lease payments and outflows (including down payments and any deferred payment for a residual value where relevant) is less than the present cost of all outflows for the credit purchase over a comparable period of leasing or ownership.

Unfortunately, difficulties arise that make this criterion less than straightforward for many consumers. One problem is properly accounting for the streams of outflows—including acquisition charges, down payments, periodic payments, disposal charges, taxes, insurance premiums, and other outflows—that can differ in both timing and amounts under the two financing alternatives. A more basic concern is that consumers do not typically think in terms of present values, discount rates, and other elements of financial economics that are second nature to the financial analyst, even though present value is the index that brings asset acquisitions under different financing schemes into the same framework.

To help satisfy concerns that individuals did not have the necessary information available to make lease versus purchase decisions wisely, Congress in 1976 mandated consumer disclosures for leases by passing the Consumer Leasing Act. Structurally, the Consumer Leasing Act is an amendment to the Truth-in-Lending Act, which Congress established as a basic consumer protection in 1968. A recurring question since then is whether the Truth-in-Lending Act generally, including the Consumer Leasing Act component (which is unchanged since passage), meets the needs of consumers in today's marketplace.[1]

This paper examines current and proposed disclosure requirements for vehicle leasing, the largest segment of the leasing industry subject to consumer disclosure requirements, in light of consumers' information needs—including what is necessary to calculate present values, the method of comparison that places all financing methods on the same footing. First, Section II looks briefly at types of automobile leases commonly available in today's marketplace and notes some important characteristics. Section III then reviews the cash flows that arise under the most common form of consumer automobile-leasing arrangement, the closed-end operating lease, and specifies a present value equation that consumers might use to analyze their leasing decisions. Finally, Section IV examines staff proposals to revise the disclosure requirements in Regulation M, the regulation that implements the Consumer Leasing Act, in view of consumers' information needs and the regulatory burdens that the proposed changes would entail.

II. Kinds of Leases

As the leasing market has evolved over the years, the closed-end operating lease has become typical in consumer transactions, at least in the big market for automobiles and light trucks. An ''operating lease'' covers a period of time shorter than the whole economic life of an asset. There is an expectation that an asset will still have an economic value (usually called its ''residual value'') at the end of an operating lease. With an operating lease, an asset user (lessee) agrees to pay for the expected depreciation of an asset during the lease period, plus a financing or lease charge to compensate the owner (lessor) for the use of the lessor's capital, including a

[1] Congress itself is reviewing this question in the 1995–6 session as members in each house have introduced bills to amend both Truth in Lending and the Consumer Leasing Act.

profit. Common car rentals or apartment leases are examples of short-term operating leases.

Also increasingly familiar today are longer-term operating leases (possibly up to 4–5 years) that auto dealers offer consumers through leasing companies and banks. These operating leases have become important substitutes for purchase financing for consumers and are widely advertised by both automobile manufacturers and dealers. Like a car renter or apartment lessee, a vehicle lessee under these plans uses the asset for a term but must return it to the lessor at the end of the lease period (unless the parties make some other arrangement for disposition). An operating lease always assumes the asset will have some remaining economic life and value at lease end. Consequently, transfer of ownership at lease end (to the lessee or another party) requires additional payment for the residual value.[2]

Among operating leases for consumers, the ''closed-end'' operating lease, sometimes referred to as a ''walk-away'' lease, has become the most common form of automobile lease agreement. On a closed-end operating lease the lessee has no obligation concerning the market value of the lessor's asset at lease end. The agreement merely requires the consumer to return the asset at lease end and to pay then for any excess damage above normal expected wear and tear.[3] Common, long-term, closed-end lease agreements for automobiles and trucks typically contain an option for consumers to purchase their vehicles at lease end at a price agreed upon at the outset, but there is no obligation to purchase.

The closed-end operating lease contrasts with the less common ''open-end'' operating lease where the lessee still does not have a requirement to purchase but where there is an obligation at lease end to make up to the lessor any shortfall in the actual market value of the asset from expectations. In effect, the open-end lessee guarantees the residual value of the lessor's asset. Under typical open-end automobile lease contracts, consumer lessees also may purchase their vehicles at lease end for a purchase price guaranteed at the outset, but open-end lessees cannot walk away. Rather, if they return their vehicles, they are liable for any differences between assumed residual values and actual, realized market values at lease end.[4]

From this description it is easy to see that the embedded fixed-price purchase options in common, closed-end operating leases for vehicles present consumers with different risk characteristics on their transaction than purchase financing. Closed-end lessees do not bear any risk of decline in the residual value of used assets below expectations over the lease period, but open-end lessees and purchasers do. If at lease end the value of the asset is below the deferred purchase price set at the outset, the closed-end lessee may return the asset and walk away. If, in contrast, the market value at lease end is greater than expected, the lessee may keep the asset by paying the deferred purchase price agreed upon at the signing of the lease and can retain it or sell it. For the closed-end lessee this amounts to a ''heads I win, tails you lose'' proposition, at least with respect to the residual value of the asset. It seems reasonable to suppose that lessors will charge closed-end lessees for the purchase option feature that transfers the residual-value risk to the lessor. Purchasers and open-end lessees bear this risk themselves. Ultimately, it is this difference in risk bearing, together with differences in the size and timing of cash flows (discussed in the next section), that characterizes the distinction for consumers between leasing and purchase financing.

III. Cash Flows

Before examining proposals for disclosures on consumer vehicle leases, there is some usefulness in examining the cash flows that arise from lease and purchase-financing contracts. Ultimately, it is comparison of the present values of the outflows that arise under the different financing schemes that resolves the question of best choice.

In the long run in a competitive, perfect capital market with full information and without transaction costs or taxes, the type of financing arrangement for retail purchase of automobiles by consumers would be a matter of indifference to both consumers and creditors/lessors: both costs to consumers and yields to creditors and lessors would be the same under the two financing alternatives. Clearly, capital markets are not perfect, however. First of all, there are transaction costs that may differ between leasing and debt financing. Also, taxes may differ between consumers and lessors, as well as between financing schemes, and there may be risk differences among consumers and among types of transactions. On occasion there also may be marketing promotions that encourage one transaction form over the other. Consequently, at different times leasing may be more or less advantageous than purchase financing to either consumers or creditors/lessors, and both consumers and creditors/lessors have an interest in evaluating the alternatives.

Fundamentally, consumers should choose a closed-end operating lease instead of debt financing only if the present value of all the costs (outflows) arising from the lease (including any down payment) is less than the present value of outflows resulting from the credit purchase over a comparable period of leasing or ownership.[5] The present value of the purchase option embedded in a closed-end operating lease, which the consumer also pays for as part of the lease payments, must be subtracted from the present value of the lease payments in order to maintain comparability between the packages of transportation-related services purchased. This presents the following decision criterion:

If Sum PV (LP) − PV (Option) < Sum PV (FP), then lease, where PV ( ) = Present Value (of quantity in brackets),

LP = all payments on a lease,
FP = all payments on a financed purchase, and
Option = Value to lessee of purchase option.

That is, if Sum PV (FP) + PV (Option) − Sum PV (LP) > 0, then lease. (1)

To analyze the decision, a consumer should discount the leasing flows at the annual percentage rate available on the credit purchase or loan. If the discounted present value of the credit flows (which equals the purchase price) plus the present value of the option is greater than the discounted present

[2] The alternative to an operating lease is a ''full-payout'' or ''financial'' lease, which finances the whole economic life of an asset by fully paying for (amortizing) the asset's capitalized cost, plus financing charges. Financial leases are not common in consumer leasing; they are more common in commercial leases and sale-leaseback transactions involving industrial buildings and equipment.

[3] There may be a refundable security deposit to guarantee payment for damages. For automobiles there may also be a small ''disposition'' or ''drop off'' charge specified in the contract. The typical automobile lease contract also specifies a yearly average mileage limit to avoid having charges for excess usage collected at lease end.

[4] The Consumer Leasing Act limits a consumer's liability for the difference between expected and actual market value on an open-end vehicle lease to no more than three times the amount of the monthly payment. This provision likely has encouraged the use of closed-end leases by making open-end leases less useful to lessors as a way of shifting risks to their customers.

[5] Although the discussion here concerns comparing a lease with a purchase, comparing two leases or two purchases would proceed in fundamentally the same way.

value of the leasing flows, then leasing is the better choice and vice versa.[6]

Leaving aside the question whether consumers understand present values and the discounting process, the difficult matter in analyzing the decision is to specify the flows properly for the two kinds of arrangements. Typically, they will differ in form, timing, and amount. Also, valuing the purchase option available on a closed-end lease might become an important aspect of the decision.[7]

Table 1 provides a listing of the four possible patterns of cash outflows arising from (1) a closed-end lease and (2) a purchase agreement for an automobile. For the lessee there are two possibilities at lease end: the lessee may return the vehicle to the dealer or may exercise the purchase option and buy it. For the credit purchaser there are also two possibilities at the end of the payment period: the owner can keep the vehicle or sell it. The table adopts the convention that outflows are positive and inflows negative; thus, the table expresses net costs of the transactions.

Initial Flows. Under this convention, the consumer receives from a lease or a financed purchase an inflow (negative cost) of transportation and other services from the vehicle during the period covered by the agreement.[8] Over comparable time periods the transportation services are assumed to be independent of the financing method (line 1 of Table 1).[9]

Some of the initial outflows arising from the two alternative financing methods will also be the same between the alternatives, but some will differ. For both types of financing the consumer agrees to a series of outflows to satisfy the payment obligation. Frequently, the first of these is a trade-in of a vehicle already owned by the consumer (line 2 in the table). With the assumption that the consumer trades in the same vehicle under both financing schemes, the trade-in is the same under the two alternatives; this is denoted in the table by equal signs between columns.

Often the trade in is accompanied by a cash down payment (line 3). (On a lease the down payment and the trade in are often called the ''capitalized cost reduction.'' In Table 1 this term applies to the cash component.) A lessee typically must also provide a security deposit, which often approximates one monthly payment on the lease obligation (line 4). Upon satisfaction of the lease agreement this security deposit is refunded at lease end (line 5).

Periodic Flows. In addition to these initial outflows, the consumer is also obligated for a series of further cash payments over the agreement period, usually monthly (line 6). On a lease the first payment typically is due at signing, while a credit-purchase agreement normally defers the first payment for a month. In many jurisdictions vehicle owners are also subject to personal property taxes on their vehicles owned or ''garaged'' within tax districts such as counties or states (line 7). On a lease in some jurisdictions the lessor may be responsible for these taxes, which it recoups by upping the necessary periodic payments. Consequently, for lessees the flows for personal property taxes may not appear as a separate, explicit outflow on a lease in many tax jurisdictions, even if personal property taxes are explicit for financed purchases. For comparability with a credit purchase, therefore, either the taxes in these jurisdictions must be subtracted from the lease payments or added to the finance payments.[10]

End-of-Term Flows. End-of-term outflows also differ between purchasing and leasing. In the credit purchase case the consumer owns the vehicle at the end of the financing period and holds the right to continued transportation services over the additional expected life of the vehicle; with a lease the consumer does not have this right. To compare a lease with purchase financing, it is necessary to account for the remaining transportation services at lease end.

One possibility, of course, is that the consumer purchases the leased vehicle at the end of the lease period, thereby obtaining the remaining transportation services. On a typical closed-end lease the consumer obtains the vehicle and its remaining services by purchasing it at the optional purchase price disclosed in the original lease agreement, or at some other price negotiated between the parties. This price becomes another outflow (line 8), this one deferred until the end of the lease period.[11]

Because the lessee does not have to make the decision whether or not to retain the vehicle until the end of the lease period, at the outset the deferred decision amounts to a call option for the lessee, and, as noted previously, this option has value because it transfers risks of residual price fluctuations to the lessor. In effect, when lessees contract for the services of vehicles, they obtain options to call the residual values of their vehicles at the end of the leases by paying at lease end a deferred optional purchase price agreed at the outset. This differentiates the lessee from the credit purchaser who owns the vehicle and bears all of the residual price risk. To maintain comparability with a purchase, the present value of this option must be subtracted from the present value of the lease costs or added to the present value of the purchase-finance costs (see equation 1, above).

The other possibility is that the consumer returns the vehicle to the lessor at lease end, thereby giving up any claim to transportation services

[6] Because discounting the flows from a financed purchase at the annual percentage rate paid for the credit equals the price of the asset, substituting the price of the asset for the discounted present value of the finance flows produces a standard net advantage of leasing (NAL) equation (see Myers, Dill, and Bautista [1976]). Substituting into equation 1 produces the decision criterion:

If NAL = Purchase Price (FP) + PV (Option) − Sum PV (LP) > 0, then lease.

[7] As a practical matter, the value of this option may not be very great to the extent that lessors are reasonably competent in predicting values of used assets in the future and set residual values and optional purchase prices at lease end accordingly.

[8] Services provided by the vehicle may also include psychological services such as pride of ownership or opportunity to drive a new or stylish automobile or truck, and in the past these psychological services may have varied depending on whether the transaction was a purchase with financing or was a lease. For example, it is possible that at least some drivers felt better thinking they ''owned'' a vehicle rather than they merely leased its services. Leasing has recently become such a common financing alternative, however, that it seems reasonable to assume that these psychological services are similar for purchase financing and leasing today and that they are of comparable value. Differences that may have existed formerly may be ignored today.

[9] Transportation services may differ between the leasing and the purchase financing cases if the amount of yearly mileage permitted under a lease without an additional mileage charge (typically 12,000 or 15,000 miles per year, but with variations) constrains the potential purchaser. For illustrative purposes this limitation is assumed not to be binding so that transportation services provided by the leased and financed vehicles are the same for this example. If the constraint were binding because the potential lessee intends to drive more than the yearly maximum, then another term for the present value of the expected deferred excess mileage charge due at lease end would be added to column 2 of the table.

[10] Identifiable personal property taxes may be deductible from adjusted gross income for federal and state income tax purposes for some consumers, which also should be properly taken into account by those eligible for the deduction. There also may be sales taxes associated with both the credit purchase and the lease. For comparing a purchase to a lease, both must be accounted for properly to avoid erroneous conclusions. For example, on a purchase sales taxes may be financed as part of the gross purchase price and paid for through the down payment and periodic payment flows. On a lease they may be collected monthly as part of the monthly payment, either explicitly or not. Each of these possibilities requires an adjustment in the table to account properly for the facts of individual situations.

[11] This purchase price may also be financed, in which case the price becomes another stream of outflows. The lessor and lessee may also agree to another lease or to a continuation of the old lease agreement. The examples in the table do not reflect these possibilities.

remaining in the vehicle. In this case the lessee returns the vehicle and pays any drop-off or disposition charge in the contract (line 9), but not any optional purchase price (line 8 is zero in this case).[12]

Purchasers who sell their vehicles receive a wholesale selling price upon sale (line 10 in the table). Those who sell them privately and not to a dealer may receive an amount closer to the retail price (if the cars are in good condition), less, of course, their costs of selling, including advertising expenses and the costs of personal time spent on the sale process (and subjective personal costs of any accompanying aggravations).

Contingencies. Two contingencies might lead to additional outflows. First, there is a chance that a vehicle may be worth more or less at the time of eventual disposition than the consumer expects at the outset, which may be important to the consumer in some cases. If the consumer expects to purchase the vehicle at lease end or plans to retain the vehicle at the end of the purchase finance period, however, planned disposition likely will take place long enough into the future that the consumer may well not have at the outset any expectation about the value many years hence. If so, this contingency probably need not enter into the present value calculations at the outset of the transaction (or into columns 1 or 3 of Table 1).[13]

In the other situation, that is, if the consumer does not intend to retain the vehicle at lease end or plans to sell the purchased auto, the time before expected disposition is shorter and unexpected loss may become a factor in decision making. For the closed-end lessee the lessor bears this risk; the value to the consumer of avoiding the loss is subsumed into the value of the call option on the vehicle's residual value. Thus, of the four cases only the purchaser who plans to sell the vehicle upon completion of the payments is subject to this potential risk (column 4 on line 11 in the table).[14]

A second contingency is the chance of a loss upon an early termination of the lease or upon a sale of the vehicle before the end of the credit-purchase agreement period. A loss on early termination might occur following theft or an accident not fully covered by insurance, or because the consumer desires to change vehicles before the end of the lease or purchase financing agreement. For both lessees and purchasers this risk is independent of plans to retain the vehicle or not at the end of the payment period and can be assumed equal for all lessors or all purchasers (indicated by equal signs on line 12 of Table 1). Since a loss (outflow) is more likely than an unexpected gain under these circumstances, however, the expected value is probably positive. To minimize the size of such losses for lessees in the cases of accident or theft (and the financial and legal difficulties that might arise) ''gap insurance'' often is available from lessors, typically included as part of the leasing transaction and charge. For most consumers, though, either the prior probability of unexpected early termination (and, consequently, the expected value of any associated loss) is probably small enough in the consumer's mind at the outset of the transaction, or the expectation of a difference in loss size in this area between leasing and purchase financing is probably small enough, that expectation of a loss on early termination is probably not much of a factor in the choice between leasing and financing.[15]

Now, the quantities in Table 1 can be substituted into equation 1 to derive the net advantage of leasing, first, for the case where the consumer keeps the vehicle at lease end (equation 2); and, second, for the situation where the consumer does not retain the vehicle (equation 3).

To ease solution, a few simplifications of the equations are possible. First, because Transportation Services (line 1 of Table 1) are assumed to be the same for comparable periods of ownership and lease holding, they may be ignored and omitted from the equations. Likewise, since the trade in is the same (line 2), it may also be dismissed. Third, if the expected value of the loss from an early termination (line 12) either is not very large or does not differ much between a financed purchase and a lease, it also can drop from the equation, since it is the difference between these quantities for a financed purchase and a lease which would enter the equation anyway. Thus, with these assumptions and recalling that leases but not purchases commonly require one monthly payment in advance, this leaves the following specifications for equations 2 and 3 for finance and lease periods of N months:

(2), (3): See Equations (2) and (3) at the End of the Analysis

These equations exhibit some features that should receive special mention. First, as discount rates move higher but other things are equal, leasing becomes relatively more attractive. Specifically, in the case where the vehicle is retained (equation 2), higher discount rates make leasing more attractive because higher discount rates relatively reduce the discounted future purchase price of the leased vehicle. This decreases the second (subtracted) term in equation 2 (the term in square brackets), tending the equation toward a positive value favoring leasing. In contrast, where the vehicle is not retained at contract end (equation 3), higher discount rates favor leasing for a different reason. In this case as the discount rate rises, it relatively decreases the present value of the sale price of the vehicle in the future. Since this is a subtracted item in the first part of the equation, higher discount rates again increase the likelihood that the equation will be positive, again tending to favor leasing relatively.

Second, the non-retention case (equation 3) requires a term, the future sale price of the vehicle, that is not known at the outset of the transaction. Even if an expected used car price some time in the future is available from some guidebook, there is no certainty concerning this price, and there is no certainty about advertising, sales and aggravation costs that properly should reduce the final sales price. Consequently, equation 3 requires some estimating and cannot serve as a definitive guide.

Third, both equations 2 and 3 contain a term for the discounted value of the purchase option available on a closed-end operating lease. Estimating the value of this option is not a simple matter, although its value may not be very great to the extent that experienced automobile dealers are reasonably proficient at estimating the values of used vehicles some time into the future.

In sum, a consumer's informed choice whether to lease or purchase an asset like a vehicle depends on the amount and pattern of the stream of outflows

[12] The lessee still acquires the purchase option, even if the ultimate decision is to return the vehicle at lease end, and so the present value of the option remains a term in equation 1, above.

[13] Even if there is a recognized prior probability of deferred gain or loss, there is no reason to expect a difference if original acquisition is through a lease or purchase contract. If loss expectations are equal at the outset, they can be ignored in the calculations (and the table) when making comparisons.

[14] For such a purchaser who plans to sell there is the real possibility of an unexpected loss upon disposition of the vehicle, but there may also be an unexpected gain. If the likelihood of the loss or gain is unknown at the outset of the lease arrangement, it might be argued that the expected value of the distribution of possibilities may well be zero, arguing for its dismissal from the calculations and the table. Because the risk of loss exists, however, an expected value of loss upon disposition is a potential outflow for a purchaser (column 4, line 11).

[15] This is not an argument against required disclosure of the existence of such a risk, however.

and on the discount rate that converts the stream of outflows to present values. Unfortunately, presence in a closed-end lease of a purchase option with unknown value and consumer uncertainty about future used-car prices mean that the single-equation optimal decision criterion will always contain multiple unknowns and be insoluble mathematically, even if the discount rate is known. Consequently, the search is not for the perfect set of disclosures, but rather for the set that enables most consumers to make good decisions most of the time.

IV. Required Disclosures

Staff proposals to revise Regulation M would make substantial changes to the format and content of required disclosures on consumer leases. In analyzing this (or any) disclosure regime, a few general principles seem useful:

(1) The goal of a disclosure scheme should be to make available sufficient information that consumers can make good decisions, not to require every disclosure that might possibly be useful to someone, sometime, for some purpose. No disclosure scheme, it seems, will ever be able to insure that all consumers understand everything or that they never have to read contracts or make any calculations for themselves. Required disclosures can be used to compare features of transactions, but cannot reasonably be specific to individuals whose situations will differ.

(2) Whenever possible, disclosures should discourage obvious opportunities for abuses.

(3) Regulatory requirements (and changes in requirements) should maintain a reasonable balance between costs and benefits.

(4) Transaction-specific disclosures are the most costly and should demonstrate clear benefits.

Avoiding the issue whether the Consumer Leasing Act itself satisfies these requirements, it appears that the proposed redrafted Regulation M does so, within the constraints of the law. The redrafted regulation mandates that lessors make substantial changes in the format and content of required disclosures, but it seems that the new approach will improve the quality and accessibility of useful information to consumers. Furthermore, much of the leasing industry supports the bulk of the proposed changes.

It does not seem, however, that any leasing-disclosure scheme can provide all of the information required for consumers to solve equations 2 or 3 for the theoretically correct choice between a lease and a financed purchase. First of all, leasing disclosures cannot reasonably be expected to provide information about the purchase-financing alternative to a lease, which is necessary to solve either equation. Consumers would have to obtain this information themselves by shopping, even if this merely means obtaining the necessary information from the same dealer. Second, some information like personal property taxes and an individual's personal tax situation are idiosyncratic to each shopper and must be factored into the purchase or lease decision by that person. Third, as already mentioned, both equations 2 and 3 require some information, such as future prices of used vehicles and the present value of the purchase option, that is not readily available to either party to the transaction except by crude estimation.

For these reasons, it does not seem reasonable to expect that any disclosure scheme will provide all the information that a consumer might find useful; it simply is not possible. Nonetheless, most of the information that consumers might need to characterize a lease is available from the required disclosures. Moreover, the new disclosure scheme should make this information easier for consumers to comprehend and use.

The proposed regulation redraft does require disclosures of some transaction-specific numerical quantities beyond those mandated by the statute, which is quite detailed. In those cases where the proposed redraft extends the law it appears, for the most part, to respond to consensus of both industry and consumerist comments that such requirements would be useful. Except for the quantity called the ''total of payments,'' all of the new numeric disclosures are amounts that lessors already calculate and have readily available. For this reason disclosing most of these additional quantities, even though not required by statute, may not by itself cause substantial marginal cost as part of a complete revamping of the disclosure regime. Proposed major changes to the regulation include the following:

(1) *Formatting Changes.* The new disclosure plan will require substantial changes in disclosure format for all lessors. Especially notable are first, the requirements for segregation of a group of key disclosures in a highlighted ''federal box''; and second, disclosure of elements that comprise the monthly payment in a mathematical progression. Although a segregated ''federal box'' of disclosures and a mathematical progression are not required by the statute, they follow the general approach for credit disclosures that became part of Regulation Z under the Truth-in-Lending Act amendments of 1980. Third, staff also proposes requiring a new format for itemization of the amount due from the consumer at inception of the lease, disclosures already required. Under the proposed format in this area, itemization of amounts due at signing would be in two columns, one listing amounts due at signing and the other designating means of paying the itemized costs.

It appears that the proposed new requirements for formatting in all three areas could help consumers become aware of important terms without searching through the contract, as is sometimes necessary today. At present, Regulation M contains no placement requirement for the key disclosures except that they be clear, conspicuous, in meaningful sequence, and that they be on the same page and above the lessee's signature. Otherwise, lessors may spread the disclosures through the contract document. For disclosing monthly payments, the current requirement is disclosure of the total amount required plus identification of the components; the regulation does not currently require disclosure of the amounts of the individual components, although some lessors have disclosed amounts of components and there has been some confusion concerning exactly what is required. Presentation of a mathematical progression should help interested consumers understand the intricacies of their transactions. The new requirement for placement of disclosures of amounts due at lease signing should help clarify questions consumers may have about any of these quantities.

Even though the proposed format of the segregated key disclosures, the mathematical progression, and the amounts due at lease signing are not required by the Consumer Leasing Act, comments from the automobile leasing industry largely support such requirements. The automobile leasing industry originally proposed both the segregated key disclosures and the mathematical progression to the monthly payment, and industry comment letters have strongly favored them since. The new requirement for a two-column disclosure of amounts due at lease signing merely calls for a reorganization of current disclosures.

In all three areas the new disclosure placement requirements would replace the current mandates concerning type size, sequencing, and placement on the same page as the lessee's signature. In the past these requirements have, on occasion, caused lessors some difficulties in form design anyway.

Sufficient lead time before a mandatory compliance date could minimize any disruptions caused by the necessity of redesigning and reprinting disclosure forms and of reprogramming computer systems to print the new forms. In addition, staff has proposed new model disclosure forms with segregated disclosures and mathematical progression. Use of these model forms ensures compliance and provides a safe harbor from liability if the form is used properly.

(2) *New Disclosures Associated with the Mathematical Progression Leading to the Monthly Payment.* As indicated above, the revised regulation also requires some new disclosures. They include disclosure of gross capitalized cost, adjusted capitalized cost, residual value, rent charge, and total of payments. Except for total of payments, these new disclosures arise as components of a mathematical progression leading to the monthly payment. There are also requirements for calculating and disclosing certain subtotals. Gross capitalized cost is analogous to gross purchase price including lease acquisition charges, carried-over balances on any previous transactions, initial taxes owed, registration fees, delivery charges, and any after-market products such as extended warranties. Adjusted capitalized cost is gross capitalized cost less ''capitalized cost reductions'' including trade-in allowances, cash down payments, rebates, and any other reductions. The residual value of the lease is the estimated value of the asset at lease end. The rent charge is the lessor's added-on charge to cover transaction costs and the charge for capital use, including any profit from financing.

Lessors determine periodic payments by subtracting the capitalized cost reductions and lease residual from the gross capitalized cost and adding the rent charge. They then divide the resulting quantity by the number of periods to determine the size of the base periodic payments, excluding any added amounts for taxes and insurance. Thus, each of these new disclosures (gross capitalized cost, adjusted capitalized cost, rent charge, and lease residual) are amounts that lessors must have readily available to make their calculations, although there has previously been no requirement for their disclosure. Likewise, newly required subtotals like total capitalized cost reduction (including cash component, trade in, and rebate or other noncash component) and amount to be depreciated and amortized (adjusted capitalized cost less lease residual) are directly derived from amounts already calculated and do not represent departures into a new disclosure scheme.

As noted above, the automobile leasing industry has supported requiring these additional disclosures as part of the development of a mathematical progression leading to the monthly payment. Apparently, some of the industry commentary favoring these disclosures arises from a concern reported from time to time in the press that some dealers may, on occasion, take advantage of potential lessees by raising the capitalized cost of a vehicle and then not disclosing the amount. Because both monthly lease payments and early termination penalties are based on this term, the concern has been that nondisclosure has the potential to permit abuses. Although all of these disclosures are transaction-specific, they are already calculated by the lessor for each transaction and are, therefore, readily available.

One additional new disclosure, the total of payments, is not part of the progression leading to the monthly payment, but it is merely another calculation based on quantities already disclosed or readily available, Thus, it should not be especially costly for lessors to produce as part of a revised disclosure scheme. It consists of the sum of the amounts due at lease signing plus the total of the periodic payments (payment amount times number of payments) plus other charges (likely to consist largely of disposition fees and taxes).

Although disclosure of the total of payments may be useful to consumers on some occasions, it may not be especially useful for shopping purposes on others because the total will vary directly with the value of the vehicle and maturity of the lease, other things equal. Consequently, even if it is useful in some cases for comparing amounts on competing leases with similar terms, it will be less useful for comparing leases on different vehicles or on the same vehicle for different lease maturities. Also, it is not a present value, and the present value of any particular amount can vary substantially with different timing patterns of outflows.

Even if these new disclosures have the potential to improve consumer protection and most appear to be favored by at least most of the automobile leasing industry, they will undoubtedly entail some additional cost. They may also be somewhat controversial among dealers, as opposed to lessors, because the new disclosures may limit their flexibility and will cause them to have to learn about new disclosures and forms. If the effective date of any final rule in this area is sufficiently deferred, however, it will minimize the difficulties of transition. Also, the cost of reprinting forms and reprogramming systems will largely be borne by lessors, who appear to be favorably inclined to the proposal, rather than by dealers.[16]

(3) *Other New Disclosures.* Staff also proposes some additional new disclosures that would appear below the monthly payment calculation on the model form. These include a warning to consumers that they may be liable for excess wear and use (including the amount of any excessive mileage charge), disclosures concerning any purchase option at lease end, and a direction that consumers refer to the rest of the disclosure statement or the contract for a list of other Consumer Leasing Act disclosures. Since all but the purchase-option price, if any, these are not transaction-specific disclosures and lessors can pre-print them on disclosure documents, these changes to the regulation should not be especially costly either, since lessors will be reprinting forms anyway as part of the change to the new disclosure scheme. The purchase-option information can be preprinted (except for the price itself, which may even be hand written).

Another preprinted disclosure requires special mention. The Consumer Leasing Act and Regulation M require lessors to disclose the ''amount or method'' of determining any charge for early termination of a lease and that the amount be ''reasonable.'' Most lessors have disclosed the method of determining the charge, but this approach has generated litigation and a finding by a United States Court of Appeals that a common disclosure violates the Regulation M standard ''that disclosures be in a reasonably understandable form.''[17]

Lessors contend that calculation of prepayment penalties is inherently complicated and, therefore, difficult to describe because of requirements of the accounting principles involved. Consequently, they have requested a determination that disclosure of the name of the method of determining the charge be sufficient, possibly with

[16] Interestingly, although these new disclosures might help prevent abuses and are, consequently, consistent with general principles outlined above for reasonable disclosure requirements, they are not needed for calculating the present value of a stream of outflows arising from a lease, since they are not cash outflows. (Therefore, they do not appear in Table 1.)

[17] Official Staff Commentary on Regulation M, Paragraph 4(a)(1)(1). See *Lundquist vs. Security Pacific Automotive Financial Services Corp.*, 993 F.2d 11, 14–15 (2nd Circuit, 1993).

approved model descriptive clauses as part of the regulation. Instead, staff has recommended requiring in the segregated disclosures a printed warning of the potential for a substantial charge for early termination, plus a full description in the disclosures outside of the segregated grouping of the method of calculating the penalty. This description would comply with the Consumer Leasing Act and Regulation M even if complex, as long as it is full, accurate, not intended to be misleading, and (as the statute requires) it is reasonable.

These generic disclosures, including the printed warning and full description of the methodology for calculating an early termination penalty, should not entail much additional cost because they could be preprinted on disclosure and contract forms. The alternative, proposed last year, of requiring a numerical example of the penalty for early termination likely would entail more substantial cost because it is specific to each individual transaction and could not be preprinted. Unlike gross capitalized cost and most of the other newly required disclosures, this amount is not currently calculated for each transaction by current calculating systems and would, therefore, require substantial system alterations. It entails estimating the market value of used assets at a second point in time for each transaction, one year into the lease as well as at lease end. Furthermore, relatively few actual prepayments would closely fit the timing of the example, since most accounts do not prepay precisely at that time. Thus, there could exist the possibility of good-faith mistakes to which civil liability would apply with only limited correspondence to actual transactions. The current proposal minimizes this possibility.

(4) *Advertising Disclosures.* Under the current regulation, advertised lease transactions that state certain terms trigger the requirement that there be other disclosures as well. Staff believes that there has been some ambiguity concerning disclosures of amounts due at the outset of leasing agreements and that the proposal would clarify the requirements. The proposal would not require itemization of amounts due at the outset, but it would require disclosure of the total with no component being more prominent in the advertisement than the total. Although the proposal will require all advertisers to become aware of the changed regulation and may be costly to some who must change their procedures, it should also make advertisements more readily comparable for consumers.

The ''trigger-term'' feature of the Consumer Leasing Act appears to have reduced the number of radio advertisements, since time often is very limited and advertisers desire to use the time for their preferred messages. In television advertisements it has produced the widely-discussed phenomenon of minute and/or scrolling type, which appears briefly at the bottom of the advertisement. A variety of observers, including attorneys general of some states, has questioned whether the use of such small type complies with the regulation or provides any useful consumer information.

As discussed in the staff memorandum, legislation in 1994 amended the Consumer Leasing Act to resolve some of these concerns for radio advertising. The statutory amendments reduce the number of disclosures that advertisements with trigger terms must contain, and they permit reference to a toll-free telephone number or to print advertisements for the full listing. Relying on the legislative history of this statutory change, staff has proposed extending this approach to television advertising as well as to radio. For radio advertisements this amendment to the regulation should somewhat reduce regulatory burden arising from the advertising provisions of the current regulation by permitting advertisers to shorten the time requirements of their broadcast advertisements. Those consumers subjected to either radio or television advertisements and who are actually interested in learning more about the product can obtain additional information without visiting either sellers or financing sources. This sort of regulatory change may become increasingly important in the future as advertisers begin to use technological innovations in advertising, such as electronic ''interactive'' advertising prepared specifically for selected audiences through new media.

(5) *The Lease Charge.* In the draft final rule staff did not include the new transaction-specific disclosure called the ''Lease Charge'' that was part of the proposal for public comment last year. This potential new disclosure was an attempt to calculate and supply consumers with a measure of the cost of lease financing analogous to the finance charge on a credit purchase. A version of this disclosure considered by the staff would have derived this measure essentially by adding to the amount of the lease rental charge 1) amounts like administrative fees that would qualify as prepaid finance charges, 2) any fees associated either with including a purchase option in the contract or associated with disposition expenses at lease end, and 3) the amount by which any optional purchase price exceeded the lease residual. The assumption behind this last addition is that if the offered optional purchase price exceeds the lease residual, then the difference must be a cost of financing. (The reasonableness of this assumption is examined further below in the following subsection, which discusses the lease rate, another disclosure considered by the staff but not included in the draft final proposal.)

The requirement for disclosure of a lease charge likely would have caused more administrative difficulties and regulatory burden than the other newly required transaction-specific disclosures. Experience with Regulation Z shows that the issue of proper inclusions and exclusions from the finance charge (and the amount financed) on credit transactions has been subject to extensive litigation in the past. Requiring a similar disclosure for leases may have led to increased litigation in the leasing area as well. Also, some questions about how to include in the lease charge fees for exercising a purchase option or for return of the asset to the lessor at end of the contract, which would never both occur on the same contract and would always occur long after contract signing and delivery of the disclosures, would have to have been answered in the Official Staff Commentary or elsewhere before the regulatory change became effective.

Apart from the likely burden of this disclosure and the potential for litigation, the lease charge in dollars would have only limited utility as a shopping tool for consumers anyway. While there may be some usefulness to disclosing the dollar cost of leasing in order to view the absolute magnitude of the agreed amount, this amount is dependent on the size of the transaction and it varies directly with maturity. Consequently, the lease charge is not especially useful for shopping among leases on different vehicles or of different maturities. Furthermore, it is merely a totalling of charges paid and payable regardless of timing; it is not a present value of these amounts. Disclosure of the method of calculating monthly payment through a mathematical progression likely will be of greater usefulness in educating consumers about the intricacies of the leasing transaction.

(6) *The Annual Percentage Lease Rate (ALR).* Many commentators discussed the usefulness of requiring disclosure of lease charges in the form of an Annual Percentage Lease Rate (ALR) analogous to the Annual Percentage Rate (APR)

required by Truth in Lending for a credit transaction. The staff memorandum discusses this issue, although the memorandum does not recommend requiring this disclosure in Regulation M. Ultimately, the difficulties with calculating and disclosing an annual lease rate arise from the necessity of assuming for a lease the value of one or more unknowns to permit solution of the discounting equation.

The mathematical formula for calculating a percentage rate from a series of cash flows is well known and straightforward: the internal rate of return formula commonly used to discount cash flows. For consumer credit, Appendix J to Regulation Z extensively describes the internal rate of return formula for ''unit period'' lengths of time, with many examples. Even an area as long established as calculating annual percentage rates on closed-end credit under Regulation Z can be subject to controversy and litigation, however, although it seems that turmoil rarely, if ever, arises from the mathematical formulas themselves. Instead, litigation comes from questions over items included or not in the formulas.[18]

If anything, leasing is more complicated on this basis than closed-end installment credit. The difficulties associated with leasing disclosures come about because on a lease a consumer does not contract for ownership of the whole economic life of the asset, but rather for only a portion of it. This fact raises questions about how to account properly for economic depreciation in the various parts of the asset's life, offers more opportunities for differing interpretations and conclusions, and even presents opportunities for manipulation.

Calculating an internal rate of return from a series of cash flows requires knowing the amount of the credit and the pattern of the cash flows (see Appendix J of Regulation Z). For installment credit like automobile financing, if assumptions are made that the contract runs to maturity and that all payments arrive as scheduled, then all of these figures are known at the outset of the transaction. On a lease they are not.

On a lease the lessee contracts only to purchase a portion of the economic depreciation of the asset and merely holds an option on the rest. For this reason, it is not possible at the outset to know the complete pattern of the flows. Some lessees will either pay or finance a balloon payment at the end of the lease term, as they acquire the vehicle by exercising their purchase option and paying the agreed-upon amount or refinancing it. Others will not purchase the vehicle and may have no intention at any time of exercising this option, and so the size of the balloon payment is irrelevant to them. Still other consumers will negotiate a continuation of the lease. To calculate a percentage rate at the outset of the lease, some assumption about the events at lease end is necessary.

Although no assumption properly describes the lease-end event for all cases, probably the most reasonable and defensible approach is to assume that the percentage rate calculation for a lease depends only on events of the lease term. This means that the calculation should not consider purchase of the vehicle or negotiated continuation of the lease. Rather, the most reasonable assumption probably is that the consumer returns the vehicle to the dealer at lease end under the terms of the lease contract. In this case the cash flows used in the calculation include only those for which the consumer is contractually liable. Other, hypothetical, possibilities do not become part of the calculation.

Under this assumption, specifying the stream of outflows during the period of the lease is relatively simple, except for the issue of valuing the purchase option. As is the case in calculating the net advantage of leasing over purchase financing (Equations 1–3, above), the present value of the purchase option embedded in a typical closed-end operating lease that permits a lessee to call the residual value of the asset at a prearranged strike price must be subtracted from the present value of the rest of the cash flows to compare the internal rate of return on a lease with purchase financing. The rest of the cash flows are straightforward. They were described in column 2 of Table 1 (see Section III, above).

Equation 4 employs these flows and using the methodology of Appendix J to Regulation Z calculates an annualized internal rate of return for a lease with these cash flows by solving for i.[19]

(4): See Equation (4) at the End of the Analysis

This is not the end of the story, though. There is still the question of lease amount, the top line of equation 4, which is necessary to solve for the ALR. On a credit transaction the amount financed is known at the outset. What is the corresponding amount of the lease?

As mentioned, a lease finances the economic depreciation of the asset during the lease period. In present value terms this is the difference between the asset price after all initial payments (called in the staff draft the ''adjusted capitalized cost'') and the present value of the residual value. Using economic depreciation as the lease amount in Equation 4 and adding the present value of the residual value to both sides of the equation produces Equation 5. Solving Equation 5 for i calculates the ALR:

(5): See Equation (5) at the End of the Analysis

Conceptually, a lessor knows all of the variables in Equation 5 at the outset of the transaction, except the value of the purchase option. Consequently, some commentators have argued, in effect, that the option be valued at zero, which is not a correct assumption, and that lessors solve equation 5 for i and disclose the result, calling it an ALR. But equation 5 has a difficulty of its own, even disregarding the inappropriateness of valuing the purchase option at zero. The remaining important problem is that the residual value used by the lessor for the purposes of making the calculations can never be better than an estimate. No one really knows what the value of the asset will be at the end of the lease, and different lessors may in good faith estimate depreciation over the lease period (and corresponding lease residual) differently. This means that in good faith they can estimate different ALR's for otherwise identical transactions. Beyond good faith differences, there is also the possibility that some market participants may want to manipulate the lease residual to alter a disclosed lease rate.

Table 2 provides an example of an automobile leasing transaction, using a disclosure format that, like the staff proposal, follows a mathematical progression illustrating the components of the calculation. Column 1 describes a hypothetical simplified example of a 24 month lease.

Assume a consumer leases a vehicle with a gross capitalized cost after all negotiations and extras of $20,000 (line 1). This consumer receives a trade-in allowance of $1000 and provides $1000 down payment in cash for a total capitalized cost reduction of $2000 (line 2). This produces an adjusted

[18] This has recently been evident in the controversy surrounding the 1994 ''Rodash'' decision, *Rodash* v. *AIB Mortgage Co.*, 16 F. 3d 1142 (11th Cir. 1994). This case was controversial enough that it prompted Congress to make some changes in the Truth-in-Lending Act itself to settle disputes over what properly is included in the components of the calculation.

[19] The term for the present value of the expected loss from early termination, which appears in Table 1, does not appear in equation 4 because it is a contingency and not predictable. Therefore, it cannot be a part of the calculation for a disclosed percentage rate.

capitalized cost of $18,000 (line 3). Subtracting a residual value for the car after 24 months of $12,000 (line 4) means depreciation of $6000 (line 5). Adding a rent charge of $1500 (line 6) results in a total of periodic payments of $7500 (line 7). A term of 24 months (line 8) means that the monthly payment amount is $312.50 (line 9). The cash flows over the course of the lease consist of the stream of 24 monthly payments of $312.50 in column 1 of the table totaling to $7500.[20]

Column 2 of Table 2 illustrates the problem of different estimates of depreciation (and corresponding lease residuals). Suppose in the example in Table 2 that another dealer/lessor estimates a higher rate of depreciation and, therefore, a lower residual value for the same vehicle. But, also suppose this dealer offers the same monthly payment by charging a lower rental fee. From a consumer's standpoint the transaction illustrated in column 2 is exactly the same as the one in column 1: the vehicle leased in the column 2 transaction is the same, the trade in allowance and cash down payment are the same (each $1000), and the pattern and total of the payments are exactly the same (24 monthly payments of $312.50 for a total of $7500). The calculated percentage rates are different, however, with column 2 leading to a lower ALR. This illustrates how different assumptions about depreciation and residuals can change the annual lease rate for the same payment stream, even apart from any issue of manipulation by dealer/lessors. If a dealer/lessor subject to a disclosure regime decides to minimize the disclosed percentage rate by lowering the expected residual for this reason, it would compound the problem.

Table 3 illustrates the difficulty of requiring disclosure of a percentage rate as the dealer/lessor engages in different marketing strategies. The three columns illustrate common marketing strategies that dealer/lessors often employ, each leading to price reductions for the consumer. The examples are constructed so that in the absence of a requirement for an ALR disclosure the dealer/lessor is financially indifferent among the strategies. Also the example is constructed so that the timing and amount of outlays is the same for consumers. Which strategy lessors choose would seem to depend on their perceptions of which strategies consumers are most likely to notice and respond to. This may vary among dealer clienteles and for any dealer over time.

Column 1 of Table 3 illustrates the common marketing strategy of raising the anticipated residual on the vehicle, thereby lowering depreciation and the size of the monthly payments, a common marketing strategy known as ''subventing'' the residual. Column 2 shows the impact of offering a ''subvented rebate'' on the lease. This has the effect of lowering the adjusted capitalized cost and the recaptured depreciation. The third choice, column 3, contains the example of a ''subvented'' rental charge. In the example this lowers the monthly payments by the same amount as the other strategies, although this time not by lowering the accounted-for depreciation but instead by lowering the rental charge component of the monthly payment. The consumer pays the same amount at the same pace in each case. Thus, from the consumer's standpoint apart from the ALR disclosure these transactions are exactly the same, but their ALR's are much different, 4.79 percent, 5.31 percent, and 0.0 percent, respectively.

To try to minimize the possibility of manipulation of residuals by lessors as a way of lowering ALR's, one alternative considered by the staff would have required that lessors not use the lease residual in their calculation of the lease charge or the Annual Lease Rate if the residual diverges from the optional purchase price. If there is a divergence, then the lessor would use the optional purchase price in the calculation under the argument that the optional purchase price represents a better estimate of the true residual value of the asset, since it is the price at which the lessor really would be wiling to sell the asset. While this approach might appear to help to minimize absolute manipulations of the residual value by lessees, it has a number of problems of its own.

One problem is that many lease contracts do not state an optional purchase price for the asset. It is possible, of course, even if perhaps not likely, that the proportion of leases without an optional purchase price could change as a result of the new disclosure regulation. Regardless of the frequency, because such leases do not contain an optional purchase price, only the residual could be used for calculations and disclosures on these leases. This would negate any purported advantage from requiring that the optional purchase price be used in place of the residual value, at least for these leases. More importantly, it would introduce a source of inconsistency into the methodology of calculations and disclosures: some disclosures would be based on lease residuals while disclosures on other leases would be dependent on optional purchase prices. It is not clear that this would solve the problem of potential for manipulation.

A second problem is that use of the optional purchase price in place of the lease residual introduces into the calculations and disclosures a quantity for which the consumer is not contractually liable. Many consumers do not purchase their leased car at lease end. Substituting the optional purchase price for the lease residual for purposes of calculating the ALR while retaining the residual for calculating the monthly payment, in effect, adds the algebraic difference between the optional purchase price and the residual to the lease charge. But, the closed-end lessee is never contractually liable for this difference at the time the dealer makes disclosures. At the outset of the lease consumers do not agree to subsequent purchase of the vehicle or, consequently, for paying the optional purchase price or the difference between it and the lease residual. In many cases lessees do not purchase their vehicles or ever pay these amounts. Thus, disclosures of a lease charge or an ALR based on optional purchase price are never right for these consumers. Even for consumers who purchase their vehicles at lease end, the price may be negotiated at that time anyway, and may well diverge from the optional purchase price originally disclosed.

A third difficulty is that the exercise price of a purchase option is not simply another estimate of the residual value of an asset. The exercise price of the purchase option may depend on the lessor's business strategy. Even if lessors have the same expectations about depreciation, they may quote different exercise prices because one may want to keep the asset and the other may prefer that the lessee buy the asset at lease end. Lessors may hedge against the possibility that certain high-demand assets may not actually depreciate very much in value over time by quoting a high, but negotiable, optional price. As a result, a lease charge or lease rate calculation that requires use of this optional purchase price, may not even approximate the lease charge or lease rate that a consumer actually pays, especially if the lessee declines to purchase the asset.

V. Impact on Small Entities

The above analysis contains a description of the implications of requiring new methods of disclosures on consumers' automobile leases. The

[20] For illustrative simplicity Table 2 ignores the complicating factors of the security deposit, refund of the deposit, disposition charge, and value of the purchase option. All except the option value could easily be added to the table.

changes will require a substantial revision to the disclosure format currently required of lessors. In issuing the new rule the Board has attempted to minimize the burden of changing to the new disclosure format by requiring, wherever possible, disclosures that can be preprinted. Furthermore, the Board took the opportunity to provide model forms to guide lessors. Section 105 of the Truth-in-Lending Act provides that a creditor or lessor that uses the appropriate model forms published by the Board ''shall be deemed to be in compliance with the disclosure provisions of this title with respect to other than numerical disclosures * * *.'' Thus, using the model forms provides a safe harbor from civil liability if the numbers are filled in accurately.

Required disclosures will be the same for large and small lessors, but the Board does not expect that the changes to Regulation M will have a substantial adverse economic impact on a large number of small entities. The automobile leasing industry, at which the bulk of the changes are directed, is highly concentrated in a small number of large firms. Actual preparation of lease documents will typically take place in the offices of numerous automobile dealers, many of which are small entities. Preparation will take place through computer terminals and computer programs provided by the lessors, however. Because the new forms are provided through the lessors' computer systems will be clearer and easier for dealer personnel to understand, explanations and necessary training of personnel should actually be enhanced and made easier for dealers.

Reference

Myers, Stewart C., David A. Dill, and Alberto J. Bautista, ''Valuation of Financial Lease Contracts,'' Journal of Finance, June 1976.

BILLING CODE 6210–01–P

Equations (2) Through (5)

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When vehicle is retained, if

$$\begin{aligned}
&\textit{Down Pay}_0 && \text{(Initial)}\\
&+ \sum_{t=1}^{N} (FP_t + PPT_t)(1 + \frac{i}{12})^{-t} && \text{(Periodic)}\\
&- [(CCR_0 + \textit{Secur Dep}_0 + LP_0) && \text{(Initial)}\\
&+ \sum_{t=1}^{N-1} (LP_t)(1 + \frac{i}{12})^{-t} && \text{(Periodic)}\\
&+ (\textit{Pur Price} - \textit{Dep Ref})(1 + i)^{-N} && \text{(End of Term)}\\
&- (\textit{Pur Opt})(1 + i)^{-N}\ ] > 0, \textit{Then Lease.} && (2)
\end{aligned}$$

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When vehicle is not retained, if

$$Down\ Pay_0 \qquad \text{(Initial)}$$

$$+ \sum_{t=1}^{N} (FP_t + PPT_t)(1 + \frac{i}{12})^{-t} \qquad \text{(Periodic)}$$

$$- (Sale - EL/S)(1 + i)^{-N} \qquad \text{(End of Term)}$$

$$[(CCR_0 + Secur\ Dep_0 + LP_0) \qquad \text{(Initial)}$$

$$+ \sum_{t=1}^{N-1} (LP_t)(1 + \frac{i}{12})^{-t} \qquad \text{(Periodic)}$$

$$+ (Disp\ Charge - Dep\ Ref)(1 + i)^{-N} \qquad \text{(End of Term)}$$

$$- (Pur\ Opt)(1 + i)^{-N}\ ] > 0, \textit{Then Lease..} \qquad \textbf{(3)}$$

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$$Lease\ Amount =$$

$$Secur\ Dep_0 + LP_0$$

$$+ \sum_{t=1}^{N-1} (LP_t)(1 + \frac{i}{12})^{-t}$$

$$+ (Disp\ Charge - Dep\ Ref)(1 + i)^{-N}$$

$$- (Pur\ Opt)(1 + i)^{-N} \qquad \textbf{(4)}$$

$$
\begin{aligned}
\textit{Adjusted Capitalized Cost} = \\
& \textit{Secur Dep}_0 + LP_0 \\
& + \sum_{t=1}^{N-1} (LP_t)(1 + \frac{i}{12})^{-t} \\
& + (\textit{Disp Charge} - \textit{Dep Ref})(1 + i)^{-N} \\
& + (\textit{ResidualValue}_N)(1 + i)^{-N} \\
& - (\textit{Pur Opt})(1 + i)^{-N}
\end{aligned}
\tag{5}
$$

BILLING CODE 6260–01–C

TABLE 1.—CASH OUTFLOWS ASSOCIATED WITH OBTAINING USE OF ASSETS THROUGH CLOSED-END OPERATING LEASES AND CREDIT PURCHASES

	Lease			Credit purchase		
	Retain auto at lease end		Turn in auto at least end	Retain auto when paid		Sell auto when paid
(1)	−Trans Serv		−Trans Serv	−Trans Serv		−Trans Serv
(2)	+Trade-In	=	+Trade-In	+Trade-In	=	+Trade-In
(3)	+CCR		+CCR	+Down Pay		+Down Pay
(4)	+Secur Dep		+Secur Dep			
(5)	−PV (Dep Ref)		−PV (Dep Ref)			
(6)	+Sum PV (LP)		+Sum PV (LP)	+Sum PV (FP)		+Sum PV(FP)
(7)				+Sum PV (PPT)		+SumPV (PPT)
(8)	+PV (Pur Price)					
(9)			+PV (Disp Chrge)			
(10)						−PV (Sale)
(11)						+PV (EL/S)
(12)	+PV (EL/ET)	=	+PV (EL/ET)	+PV (EL/ET)	=	+PV (EL/ET)

Abbreviations Used:
PV ( )—Present Value (of Quantity in Brackets).
Trans Serv—Transportation Services Provided.
CCR—(Cash) Capitalized Cost Reduction.
Down Pay—(Cash) Down Payment.
Secur Dep—Security Deposit.
Dep Ref—Security Deposit Refund.
LP—Lease Payments.
FP—Finance Payments.
PPT—Personal Property Taxes.
Pur Price—Purchase Price.
Disp Chrge—Disposition or Drop-Off Charge.
Sale—Sale Price.
EL/S—Expected Loss on Sale of the Vehicle.
EL/ET—Expected Loss Upon Early Termination of Lease.

TABLE 2—PATTERNS OF DISCLOSURES

	1	2
	Base case	Lower residual
(1) Gross Cap. Cost	20,000	20,000

TABLE 2—PATTERNS OF DISCLOSURES—Continued

	1	2
	Base case	Lower residual
(2) Cap. Cost Reduction	−2000	−2000
(3) Adjusted Cap. Cost	=18,000	=18,000
(4) Residual Value	−12,000	−10,500
(5) Depreciation	=6000	=7500
(6) Rent Charge	+1500	+0
(7) Amount of Periodic Payments	=7500	=7500
(8) Lease Term	24	24
(9) Base Monthly Payment	312.50	312.50
Additional Information about Transaction		
(10) Sale Price of Vehicle	12,000	12,000
(11) Gain on Sale	0	1500
(12) Recovery of Adjusted Cap. Cost	19,500	19,500

TABLE 3.—PATTERNS OF DISCLOSURES

	1	2	3
	Subvent residual	Subvent rebate	Subvent lease charge
(1) Gross Cap. Cost	20,000	20,000	20,000
(2) Cap. Cost Reduction	−2000	−3500	−2000
(3) Adjusted Cap. Cost	=18,000	=16,500	=18,000
(4) Residual Value	−13,500	−12,000	−12,000
(5) Depreciation	=4500	=4500	=6000
(6) Rent Charge	+1500	+1500	+0
(7) Amount of Periodic Payments	=6000	=6000	=6000
(8) Lease Term	24	24	24
(9) Base Monthly Payment	250	250	250
Additional Information about Transaction			
(10) Sale Price of Vehicle	12,000	12,000	12,000
(11) Gain on Sale	(1500)	0	0
(12) Recovery of Adjusted Cap. Cost	18,000	18,000	18,000

By order of the Board of Governors of the Federal Reserve System, September 27, 1996.

William W. Wiles,

Secretary of the Board.

[FR Doc. 96–25273 Filed 10–4–96; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 96–AWP–19]

Revocation of Class D Airspace; Alameda, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final Rule.

SUMMARY: This action revokes the Class D airspace area at Alameda, CA. The base closure of Alameda Naval Air Station (NAS) has made this action necessary. The intended effect of this action is to revoke controlled airspace since the purpose and requirements for the surface area no longer exist at Alameda NAS (Nimitz Field), CA.

EFFECTIVE DATE: 0901 UTC December 5, 1996.

FOR FURTHER INFORMATION CONTACT:

William Buck, Airspace Specialist, Operations Branch, AWP–530, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725–6556.

SUPPLEMENTARY INFORMATION:

History

On August 27, 1996, the FAA proposed to amend Part 71 of the Federal Aviation Regulations (14 CFR part 71) by revoking the Class D airspace area at Alameda, CA (61 FR 44008). This action will revoke controlled airspace since the purpose and requirements for the surface area no longer exits at Alameda NAS (Nimitz Field), CA. Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposals to the FAA. No comments to the proposal were received. Class D airspace designations are published in paragraph 5000 of FAA Order 7400.9D dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The Class D airspace designations listed in this document will be removed subsequently in this Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) revokes the Class D airspace area at Alameda, CA. The base closure of Alameda Naval Air Station (NAS) has made this action necessary. The intended effect of this action is to revoke controlled airspace since the purpose and requirements for the surface area no longer exist at Alameda NAS (Nimitz Field), CA.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(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 10034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 5000 Class D airspace.

* * * * *

AWPCAD Alameda NAS, CA [Removed]

* * * * *

Issued in Los Angeles, California, on September 25, 1996.

James H. Snow,

Acting Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 96–25606 Filed 10–4–96; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 71

[Airspace Docket No. 96–AWP–10]

Establishment of Class E Airspace; Groveland, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final Rule.

SUMMARY: This action establishes a Class E airspace area at Groveland, CA. The development of a Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 09/27 has made this action necessary. The intended effect of this action is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Pine Mountain Lake Airport, Groveland, CA.

EFFECTIVE DATE: 0901 UTC December 5, 1996.

FOR FURTHER INFORMATION CONTACT: William Buck, Airspace specialist, Operations Branch, AWP–530, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725–6556.

SUPPLEMENTARY INFORMATION:

History

On August 30, 1996, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by established a Class E airspace area at Groveland, CA, (61 FR 45919). This action will provide adequate controlled airspace to accommodate a GPS SIAP to RWY 09/27 at Pine Mountain Lake Airport, Groveland, CA.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments to the proposal were received. Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9D dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in this Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) establishes Class E airspace area at Groveland, CA. The development of a GPS SIAP to RWY 09/27 has made this action necessary. The effect of this action will provide adequate airspace for aircraft executing the GSP RWY 09/27 SIAP at Pine Mountain Lake Airport, Groveland, CA.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(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 10034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air)

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 6005 Class E airspace area extending upward from 700 feet or more above the service of the earth.

* * * * *

AWP CA E5 Groveland, CA [New]

Pine Mountain Lake Airport, CA
(lat. 37°51′42″N, long. 120°10′43″W)

That airspace extending upward from 700 feet above the surface within a 5.7-mile radius of the Pine Mountain Lake Airport and within 2 miles southwest and 3 miles northeast of the 135° bearing from the Pine Mountain Lake Airport extending from the 5.7-mile radius to 11 miles southeast of the airport.

* * * * *

Issued in Los Angeles, California, on September 25, 1996.

James H. Snow,

Acting Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 96–25608 Filed 10–4–96; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 71

[Airspace Docket No. 96–AWP–16]

Establishment of Class E Airspace; Phoenix, Deer Valley Municipal Airport, AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes a Class E airspace area at Phoenix, Deer Valley Municipal Airport, AZ. The development of a Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 07R to Phoenix-Deer Valley Municipal Airport has made this action necessary. The intended effect of this action is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Phoenix-Deer Valley Municipal Airport. AZ.

EFFECTIVE DATE: 0901 UTC December 5, 1996.

FOR FURTHER INFORMATION CONTACT: William Buck, Airspace Specialist, Operations Branch, AWP–530, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725–6556.

SUPPLEMENTARY INFORMATION:

History

On September 5, 1996, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by establishing a Class E airspace area at Phoenix-Deer Valley Municipal Airport, AZ (61 FR 46744). This action will provide adequate controlled airspace to accommodate at GPS SIAP to RWY 07R at Phoenix-Deer Valley Municipal Airport, AZ.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments to the proposal were received. Class E airspace designations are published in paragraph 6002 of FAA Order 7400.9D dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in this Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) establishes a Class E airspace area at Phoenix-Deer Valley Municipal Airport, AZ. The development of a GPS SIAP to RWY 07R has made this action necessary. The effect of this action will provide adequate airspace for aircraft executing the GPS RWY 07R SIAP at Phoenix-Deer Valley Municipal Airport, AZ.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(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 10034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9665, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 6002 Class E airspace areas designated as a surface area for an airport.

* * * * *

AWP AZ E2 Phoenix, Deer Valley Municipal, AZ [New]

Phoenix, Deer Valley Municipal Airport, AZ
(lat. 33°41′18″N, long. 112°04′56″W)

* * * * *

Within 3 miles south and 2 miles north of the 287° bearing from the Deer Valley Municipal Airport extending from the 4.4-mile radius of the Deer Valley Municipal Airport to 9.2 miles west of the airport.

Issued in Los Angeles, California, on September 25, 1996.

James H. Snow,

Acting Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 96–25607 Filed 10–4–96; 8:45 am]

BILLING CODE 4910–13–M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 232

[Release Nos. 33–7351; 34–37774; 35–26585; 39–2343; IC–22257]

RIN 3235–AG96

Adoption of Updated EDGAR Filer Manual

AGENCY: Securities and Exchange Commission.

ACTION: Final rules.

SUMMARY: The Securities and Exchange Commission (''Commission'') is adopting an updated edition of the EDGAR Filer Manual and is providing for its incorporation by reference into the Code of Federal Regulations.

EFFECTIVE DATE: The amendment to 17 CFR part 232 (Regulation S–T) will be effective on October 7, 1996. The new edition of the EDGAR Filer Manual (Release 5.10) will be effective on October 7, 1996. The incorporation by reference of the EDGAR Filer Manual is approved by the Director of the Federal Register as of October 7, 1996.

FOR FURTHER INFORMATION CONTACT: In the Office of Information Technology, David T. Copenhafer at (202) 942–8800; for questions concerning investment company filings, Ruth Armfield Sanders, Senior Counsel, Division of Investment Management, at (202) 942–0591.

SUPPLEMENTARY INFORMATION: The Commission today announces the adoption of an updated EDGAR Filer Manual (''Filer Manual''), which sets forth the technical formatting requirements governing the preparation and submission of electronic filings through the Electronic Data Gathering, Analysis, and Retrieval (''EDGAR'') system.[1] Compliance with the provisions of the Filer Manual is required in order to assure the timely acceptance and processing of filings made in electronic format.[2] Filers should consult the Filer Manual in conjunction with the Commission's rules governing mandated electronic filing when preparing documents for electronic submission.[3] In this update, notice is provided to filers concerning the change in electronic filing requirements resulting from the elimination of fees previously adopted by the Commission under the Independent Offices Appropriations Act of 1952 (''IOAA'').[4]

In addition, several submission types have been added to accommodate existing rules. Specifically, new EDGAR submission type ''POS 8C'' has been added to accommodate filings of post-effective amendments under the Securities Act of 1933 (the ''Securities Act'')[5] by certain investment companies. This submission type is to be used by investment companies whose registration statements are filed on Forms N–2 and N–5 for the submission of post-effective amendments under the Securities Act, or for post-effective amendments under both the Securities Act and the Investment Company Act of 1940.[6] Also added for investment companies are submission types ''485BXT,'' ''485BXTE,'' and ''485BXTF.'' These three submission types are to be used by open-end investment companies submitting filings under Securities Act rule 485(b)(1)(v) to designate new effective dates for filings previously made under Securities Act rule 485(a).[7]

Rule 301 of Regulation S–T also is being amended to provide for the incorporation by reference of the Filer Manual into the Code of Federal Regulations, which incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. The revised Filer Manual and the amendment to Rule 301 will be effective on October 7, 1996.

Paper copies of the updated Filer Manual may be obtained at the following address: Public Reference Room, U.S. Securities and Exchange Commission, Mail Stop 1–2, 450 Fifth Street, N.W., Washington D.C. 20549. Electronic format copies will be available on the EDGAR electronic bulletin board. Copies also may be obtained from Disclosure Incorporated, the paper and microfiche contractor for the Commission, at (800) 638–8241.

Since the Filer Manual relates solely to agency procedure or practice, publication for notice and comment is not required under the Administrative Procedure Act.[8] It follows that the requirements of the Regulatory Flexibility Act[9] do not apply.

The effective date for the updated Filer Manual and the rule amendments is October 7, 1996. In accordance with the Administrative Procedure Act, 5 U.S.C. 553(d)(3), the Commission finds that there is good cause to establish an effective date less than 30 days after publication of these rules. The EDGAR system was upgraded to Release 5.10 on September 14, 1996, to add the new submission types and implement technical system enhancements, and upgraded again on Saturday, October 5, 1996, to implement system adjustments to accommodate the elimination of IOAA fees, in anticipation of an effective date of Monday, October 7, 1996. The Commission believes that it is necessary to coordinate the effectiveness of the updated Filer Manual with the effective date for the elimination of IOAA fees to avoid confusion for EDGAR filers.

Statutory Basis

The amendment to Regulation S–T is being adopted under Sections 6, 7, 8, 10, and 19(a) of the Securities Act,[10] Sections 3, 12, 13, 14, 15, 23, and 35A of the Securities Exchange Act of 1934,[11] Section 20 of the Public Utility Holding Company Act of 1935,[12] Section 319 of the Trust Indenture Act of 1939,[13] and Sections 8, 30, 31, and 38 of the Investment Company Act of 1940.[14]

List of Subjects in 17 CFR Part 232

Incorporation by reference; Investment companies; Registration requirements; Reporting and recordkeeping requirements; Securities.

Text of the Amendment

In accordance with the foregoing, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

1. The authority citation for Part 232 continues to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77sss(a), 78c(b), 78*l*, 78m, 78n, 78o(d), 78w(a), 78*ll*(d), 79t(a), 80a–8, 80a–29, 80a–30 and 80a–37.

2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Electronic filings shall be prepared in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets out the technical formatting requirements for electronic submissions. The September 1996 edition of the *EDGAR Filer Manual: Guide for Electronic Filing with the U.S. Securities and Exchange Commission (Release 5.10*) is incorporated into the Code of Federal Regulations by reference, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Compliance with the requirements found therein is essential to the timely receipt and acceptance of documents

[1] The Filer Manual originally was adopted on April 1, 1993, and became effective on April 26, 1993. Release No. 33–6986 (April 1, 1993) [58 FR 18638]. The most recent update to the Filer Manual was adopted in Release No. 33–7241 (November 13, 1995) [60 FR 57682].

[2] *See* Rule 301 of Regulation S–T (17 CFR 232.301).

[3] *See* Release Nos. 33–6977 (February 23, 1993) [58 FR 14628], IC–19284 (February 23, 1993) [58 FR 14848], 35–25746 (February 23, 1993) [58 FR 14999], and 33–6980 (February 23, 1993) [58 FR 15009] for a comprehensive treatment of the rules adopted by the Commission governing mandated electronic filing. *See also* Release No. 33–7122 (December 19, 1994) [59 FR 67752], in which the Commission made the EDGAR rules final and applicable to all domestic registrants and adopted minor amendments to the EDGAR rules, and Release No. 33–7241, in which the Commission adopted the most recent update to the Filer Manual and additional minor technical amendments to the EDGAR rules.

[4] 31 U.S.C. 9701. *See* Release No. 33–7331 (September 17, 1996) [61 FR 49957], adopting, and Release No. 33–7293 (May 16, 1996) [61 FR 25601], proposing, the fee elimination.

[5] 15 U.S.C. 77a *et seq.*

[6] 15 U.S.C. 80a–8, 80a–29, 80a–30 and 80a–37.

[7] *See* Release Nos. IC–20486 (August 17, 1994) [59 FR 43460] and IC–20486A (September 19, 1994) [59 FR 48798].

[8] 5 U.S.C. 601–612.

[9] 5 U.S.C. 553(b).

[10] 15 U.S.C. 77f, 77g, 77h, 77j and 77s(a).

[11] 15 U.S.C. 78c, 78*l*, 78m, 78n, 78o, 78w and 78*ll*.

[12] 15 U.S.C. 79t.

[13] 15 U.S.C. 77sss.

[14] 15 U.S.C. 80a–8, 80a–29, 80a–30 and 80a–37.

filed with or otherwise submitted to the Commission in electronic format. Paper copies of the EDGAR Filer Manual may be obtained at the following address: Public Reference Room, U.S. Securities and Exchange Commission, Mail Stop 1–2, 450 5th Street, N.W., Washington, D.C. 20549. They also may be obtained from Disclosure Incorporated by calling (800) 638–8241. Electronic format copies are available through the EDGAR electronic bulletin board. Information on becoming an EDGAR E-mail/electronic bulletin board subscriber is available by contacting CompuServe Inc. at (800) 848–8199.

By the Commission.

Dated: October 2, 1996.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–25815 Filed 10–4–96; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 355

[Docket No. 80N–0042]

RIN 0910–AA01

Anticaries Drug Products for Over-the-Counter Human Use; Final Monograph; Technical Amendment; Partial Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment; partial delay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulation that established conditions under which over-the-counter (OTC) anticaries drug products (products that aid in the prevention of dental cavities) are generally recognized as safe and effective and not misbranded (60 FR 52478, October 6, 1995). This final rule makes a nonsubstantive change in the definition of a dentifrice, clarifies how OTC dentifrice gels are included in certain labeling aspects of the final monograph, and clarifies that the second general warning regarding ''accidental ingestion'' is the statement to be used for OTC fluoride-containing dentifrice, treatment rinse, and preventive treatment gel drug products. This amendment also revises the second general warning statement to indicate to consumers that ''accidental ingestion'' of these products means swallowing more than is used during normal brushing or rinsing. Because of the need to revise labeling for this minor revision, the agency is delaying the effective date of the regulation to provide manufacturers with an additional 6 months to comply with the labeling requirements of the monograph. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

DATES: The effective date for § 355.50 added at 60 FR 52508, October 6, 1995, is delayed until April 7, 1997. This final rule is effective April 7, 1997.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–105), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2304.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of October 6, 1995 (60 FR 52478), FDA issued a final monograph for OTC anticaries drug products (21 CFR part 355) establishing conditions under which the drug products that are subject to that monograph will be generally recognized as safe and effective and not misbranded. The effective date of the monograph is October 7, 1996.

On April 17, 1996, the Joint Oral Care Task Group of the Nonprescription Drug Manufacturers Association (NDMA) and the Cosmetic, Toiletry and Fragrance Association (CTFA) (the Task Group) submitted three citizen petitions (Refs. 1, 2, and 3) to amend the final monograph for OTC anticaries drug products. The first petition requested a technical amendment to the final monograph to clarify the use of the term ''gel'' in the context of dentifrice gels and preventive treatment gels in § 355.50(c) and (d). The petition indicated that this technical amendment would be helpful in avoiding unnecessary discussion and/or confusion about how OTC dentifrice gels are included in certain labeling aspects of the final monograph.

The two other petitions requested an exemption from the requirements of the general warnings under § 330.1(g) (21 CFR 330.1(g)) for OTC fluoride-containing dentifrice, treatment rinse, and preventive treatment gel drug products based on these products' long history of safe use, the package size limitations to limit potential toxicity, and the potential for consumer confusion and alarm that the general warnings would cause.

The Task Group added that the second general warning for these drug products is confusing with regard to the terms ''accidental overdose'' and ''accidental ingestion.'' Because these products are not intended for oral administration in the context of an orally administered medicine and because no dosage amounts are specified in the labeling, there is no ''overdose'' per se. The Task Group contended that consumers may mistakenly consider any accidental ingestion (even the swallowing of some product during normal usage) as dangerous and thus needlessly call health professionals in poison control centers, emergency rooms, and doctors' offices for assistance.

II. The Agency's Response to the Petitions

Based on these petitions, the agency has determined that in order to avoid possible confusion about how OTC dentifrice gels and powders are included in certain labeling aspects of the final monograph for OTC anticaries drug products, the definition of ''Dentifrice'' in § 355.3(e) should be revised to read: ''An abrasive-containing dosage form (gel, paste, or powder) for delivering an anticaries drug to the teeth.''

To clarify how OTC dentifrice gels are included in the labeling aspects in § 355.10(a)(1), (b)(1), (b)(2), and (c)(1) and § 355.50(d)(1)(i) and (d)(1)(ii) of the final monograph, this technical amendment revises the heading in each of these sections by adding the words ''gel or'' before the word ''paste.'' To better clarify how OTC dentifrice gels and preventive treatment gels are included in the labeling aspects in § 355.50(c)(1) and (c)(2), respectively, this technical amendment includes the following revisions: (1) The heading in § 355.50(c)(1) is revised to read: *''For all fluoride dentifrice (gel, paste, and powder) products,''* and (2) the heading in § 355.50(c)(2) is revised to read: *''For all fluoride rinse and preventive treatment gel products.''*

With regard to the second general warning in § 330.1(g), the agency points out that the correct second general warning to be used for fluoride-containing gel, paste, powder, treatment rinse, and preventive treatment gel drug products included in the final monograph is the statement for accidental ingestion and not for accidental overdose. That statement reads: ''In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.'' The agency considers this information important to provide consumers guidance if an accidental ingestion occurs, particularly if a young child accidentally swallows or ingests an

excessive amount of an OTC anticaries drug product.

However, the agency recognizes that this statement may be confusing to consumers who might think that any accidental ingestion of an OTC anticaries drug product during normal use may be dangerous. Therefore, to clarify to consumers that ''accidental ingestion'' does not refer to the amount of product swallowed during normal use, but refers to excessive ingestion of the drug product, this technical amendment revises the second general warning in § 355.50(c)(1) and (c)(2) of the final monograph to read as follows: ''If you accidentally swallow more than used for'' (select appropriate word: ''brushing'' or ''rinsing''), ''seek professional assistance or contact a Poison Control Center immediately.'' The agency considers these labeling revisions as minor clarifying changes that do not change the substance of the labeling requirements contained in the final rule.

In a communication with the petitioner (Ref. 4), the agency indicated that it had not decided on the exact revised wording of the second general warning and asked the petitioner to make a suggestion. The petitioner subsequently suggested (Ref. 5) the following language: ''If an amount larger than used for [brushing] is swallowed, call a Poison Control Center or doctor right away.'' The agency considered the first part of the petitioner's suggestion in developing the language that appears in this final rule. However, the agency is not changing the wording of the second part of this statement at this time because such a change would be more than a technical amendment, which would constitute a need for notice and comment rulemaking.

In a future issue of the Federal Register, the agency intends to propose a revision to the general warnings labeling in § 330.1(g). This revision will include changes in the language of the second part of this warning statement. The agency will provide an opportunity for full public comment before establishing the revised wording and will further consider the comment's suggestion at that time. The agency does not want to implement revised labeling for that part of the warning for only anticaries drug products at this time, but will implement revised labeling for all OTC drug products uniformly at a later date.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). This final rule institutes changes that are nonsubstantive in nature. Because the revisions are not controversial and because, when effective, they provide clarification of the final monograph for OTC anticaries drug products, FDA finds that the notice and comment procedures are unnecessary and not in the public interest (5 U.S.C 553 (b) and (d)). The agency believes that delaying the effective date for 6 months will provide sufficient time for industry to implement fully the labeling revisions included in this technical amendment.

III. References

The following references are on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

(1) Comment No. CP6 (Vol. 22), Docket No. 80N–0042, Dockets Management Branch.

(2) Comment No. CP6 (Vol. 24), Docket No. 80N–0042, Dockets Management Branch.

(3) Comment No. CP6 (Vol. 26), Docket No. 80N–0042, Dockets Management Branch.

(4) Letter from D. Bowen, FDA, to R. W. Soller, Nonprescription Drug Manufacturers Association, coded as LET32, Docket No. 80N–0042, Dockets Management Branch.

(5) Letter from R. W. Soller, Nonprescription Drug Manufacturers Association, to D. Bowen, FDA, dated July 11, 1996, Docket No. 80N–0042, Dockets Management Branch.

IV. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic environmental, public health and safety, and other advantages: distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. The agency therefore concludes that none of these technical changes included in this final rule is a major rule. In addition, this final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under 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 a rule on small entities. This final rule makes a minor revision in some labeling that was to become effective on October 7, 1996, but which will not be required now until April 7, 1997. Thus, this final rule will not impose a significant economic burden on affected entities. Therefore, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commissioner of Food and Drugs certifies that this final rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required.

V. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) 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.

List of Subjects in 21 CFR Part 355

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 355 is amended as follows:

PART 355—ANTICARIES DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 355 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 355.3 is amended by revising paragraph (e) to read as follows:

§ 355.3 Definitions.

* * * * *

(e) *Dentifrice.* An abrasive-containing dosage form (gel, paste, or powder) for delivering an anticaries drug to the teeth.

* * * * *

§ 355.10 [Amended]

3. Section 355.10 is amended in the headings for paragraphs (a)(1), (b)(1), (b)(2), and (c)(1) by adding the words ''gel or'' before the word ''paste''.

4. Section 355.50 is amended by revising paragraphs (c)(1) and (c)(2), and in the headings for paragraphs (d)(1)(i) and (d)(1)(ii) by removing the word ''Paste'' and adding in its place the words ''Gel or paste'' to read as follows:

§ 355.50 Labeling of anticaries drug products.

* * * * *

(c) * * *

(1) *For all fluoride dentifrice (gel, paste, and powder) products.* ''Keep out of the reach of children under 6 years of age. If you accidentally swallow more than used for brushing, seek professional assistance or contact a Poison Control Center immediately.'' These warnings shall be used in place of the general warning statements required by § 330.1(g) of this chapter.

(2) *For all fluoride rinse and preventive treatment gel products.* ''Keep this and all drugs out of the reach of children. If you accidentally swallow more than used for'' (select appropriate word: ''brushing'' or ''rinsing''), ''seek professional assistance or contact a Poison Control Center immediately.'' These warnings shall be used in place of the general warning statements required by § 330.1(g) of this chapter.

* * * * *

Dated: September 30, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–25599 Filed 10–4–96; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1309, 1310, 1313

[DEA NUMBER 138P]

RIN 1117–AA32

Removal of Exemption for Certain Pseudoephedrine Products Marketed Under the Food, Drug, and Cosmetic Act (FD&C Act)

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule; withdrawal.

SUMMARY: DEA is withdrawing its rulemaking regarding Removal of Exemption for Certain Pseudoephedrine Products Marketed Under the Food, Drug, and Cosmetic Act (FD&C Act) which was published in the Federal Register on August 7, 1996 (61 FR 40981). The final rule has been superseded by the Comprehensive Methamphetamine Control Act of 1996, which declares the final rule null and void and of no effect.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC. 20537, Telephone (202) 307–7183.

SUPPLEMENTARY INFORMATION: DEA published a notice of proposed rulemaking (NPRM) regarding Removal of Exemption for Certain Pseudoephedrine Products Marketed Under the Food, Drug, and Cosmetic Act (FD&C Act) in the Federal Register on October 31, 1995 (60 FR 55348). The NPRM proposed certain amendments to Title 21, Code of Federal Regulations (CFR), Parts 1309, 1310, and 1313, and was open for public comment until January 2, 1996. Following the comment period, DEA published a final rulemaking on August 7, 1996 (61 FR 40981), which was to become effective on October 7, 1996. However, on September 29, 1996, Congress passed the Comprehensive Methamphetamine Control Act of 1996, which provides that ''The final rule concerning removal of exemption for certain pseudoephedrine products marketed under the Federal Food, Drug, and Cosmetic Act published in the Federal Register of August 7, 1996 (61 FR 40981–40933) is null and void and of no force or effect.'' As a result, the amendments contained in the final rule are canceled and the regulatory text of 21 CFR Parts 1309, 1310, and 1313 remains unchanged.

Accordingly, DEA's rulemaking entitled Removal of Exemption for Certain Pseudoephedrine Products Marketed Under the Food, Drug, and Cosmetic Act (FD&C Act), published in the Federal Register as a proposed rule on October 31, 1995 (60 FR 55348) and as a final rule on August 7, 1996 (61 FR 40981), is withdrawn.

Dated: October 2, 1996.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 96–25665 Filed 10–4–96; 8:45 am]

BILLING CODE 4410–09–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[OPPTS–50617A; FRL 5396–6]

RIN 2070–AA58

Benzidine-Based Chemical Substances; Significant New Uses of Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating a significant new use rule (SNUR) under section 5(a) of the Toxic Substances Control Act (TSCA) which requires persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of certain benzidine-based chemical substances for any significant new use as described in this rule. EPA believes that this action is necessary because benzidine-based chemical substances may be hazardous to human health and that the uses governed by this rule may result in significant exposure to workers handling those substances. The required notice provides EPA with the opportunity to evaluate any intended new uses and associated activities before the benzidine-based chemical substances can be introduced into the marketplace for a significant new use, and an opportunity to protect against potentially adverse exposure before it occurs.

EFFECTIVE DATE: This rule becomes effective on November 20, 1996. Persons who begin commercial manufacture, importation, or processing of listed benzidine-based chemical substances for any significant new use listed in this rule between August 30, 1995, and November 20, 1996 must comply with the requirements of this final SNUR. See Unit VII of this preamble for more information. In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern time on October 21, 1996.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxic Substances, Environmental Protection Agency, 401 M St., SW., Rm. E–545, Washington, DC 20460, Telephone: (202) 554–1404, TDD: (202) 554–0551; e-mail: TSCA-Hotline@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: This SNUR requires persons to notify EPA at

least 90 days before commencing the manufacture, import, or processing of the benzidine-based chemical substances listed in this rule for any significant new use as described in § 721.1660(a)(2). The SNUR does not apply to uses of benzidine-based substances in existence when this SNUR was proposed which include uses as: A reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; and also for Colour Index (C.I.) Direct Red 28 (Congo Red, CAS No. 573–58–0) as an indicator dye. The required notification will provide EPA with information needed to evaluate the new use and associated activities, and an opportunity to protect against potentially adverse exposure to the chemical substance before it can occur. This rule was proposed on August 30, 1995 (60 FR 45119) (FRL–4762–4).

Regulated entities. Entities potentially regulated by this action are those which manufacture, import, or process the benzidine-based chemical substances listed in the rule for any use other than those listed in § 721.1660(a)(2). Regulated categories and entities include:

Category	Examples of regulated entities
Industry	Manufacturers, importers, and processors of cyclic organic crudes and intermediates, and organic dyes.
Industry	Entities which plan to use the listed dyes in conjunction with apparel and other finished products made from fabrics, leather, and similar materials.
Industry	Entities which plan to use the listed dyes in conjunction with paper and allied products.
Industry	Manufacturers, importers, and processors of printing ink.

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 EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your business is regulated by this action, carefully examine the applicability criteria set forth in § 721.1660 of this rule. For questions regarding the applicability of this action to a particular entity, see ''FOR FURTHER INFORMATION CONTACT'' at the beginning of this document.

I. Authority

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' The Agency must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). Section 5(a)(2) factors generally relate to the extent that a use changes the volume of a chemical substance's production or the type, form, magnitude, or duration of exposure to it. Once EPA determines by rule that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before manufacturing, importing, or processing the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)).

Persons subject to this SNUR must comply with the same notice requirements and EPA regulatory procedures as submitters of premanufacture notices (PMNs) under section 5(a)(1)(A) of TSCA (15 U.S.C. 2604(a)(1)(A)). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and (d)(1), the exemptions authorized by TSCA section 5 (h)(1), (2), (3), and (5), and the regulations at 40 CFR part 720. If during its review, EPA identifies concerns, regulatory action may be taken under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received a SNUN (15 U.S.C. 2604 (e), (f), 2605, 2606). If EPA does not take action, section 5(g) of TSCA requires EPA to explain in the Federal Register its reasons for not taking action (15 U.S.C. 2604(g)).

Persons who intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)). The regulations that interpret section 12(b) appear at 40 CFR part 707. Persons who intend to import a chemical substance identified in a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements, and to the regulations codified at 19 CFR 12.118 through 12.127 and 12.128. Such persons must certify that they are in compliance with TSCA requirements. The EPA rule in support of import certification appears at 40 CFR part 707.

II. Applicability of General Provisions

General regulatory provisions applicable to SNURs are codified at 40 CFR part 721, subpart A. In the Federal Register of August 17, 1988 (53 FR 31252), EPA promulgated a ''User Fee Rule'' (40 CFR part 700) under the authority of TSCA section 26(b) (15 U.S.C. 2625(b)). Provisions requiring persons submitting SNUNs to submit certain fees to EPA are discussed in detail in the Federal Register document. Interested persons should refer to 40 CFR parts 700 and 721 and the August 17, 1988 Federal Register document for further information.

III. Introduction

A. Summary

The chemical substances that are the subjects of this SNUR are certain benzidine-based chemical substance as listed in table 1 of § 721.1660.

EPA has determined that there is no ongoing manufacture, import, or processing, of the listed benzidine-based chemical substances, except for the ongoing uses of such substances in small amounts for a few, limited purposes (identified in § 721.1660(a)(2) of this rule). Because the listed benzidine-based chemical substances are currently only used for these limited purposes, EPA is concerned that any new use beyond the current ongoing limited uses would increase production volume resulting in increased potential for exposure to workers which would be significant because of their potential carcinogenicity. Therefore, under TSCA section 5(a)(2), EPA is designating any use of the listed benzidine-based chemical substances as a significant new use, other than the following ongoing uses of such chemical substances: As a reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; and also for C. I. Direct Red 28 as an indicator dye.

Except for the ongoing uses listed above, this rule requires persons who intend to manufacture, import, or process the benzidine-based chemical substances listed in table 1 of § 721.1660 of this rule to notify EPA through the submission of a SNUN, at least 90 days before commencing the manufacture, importation, or processing of any of these substances for the significant new uses designated in this SNUR. The required notice provides EPA with the opportunity to evaluate the intended use, and, if necessary, to prohibit or limit that use before it occurs.

B. Final Rule—Changes From the Proposed Rule

The Agency reviewed all comments received on the proposed rule. After consideration of issues raised by the commenters, the Agency has taken the following actions:

1. Some inconsistencies in naming and inaccuracies in CAS numbers in table 1 of 40 CFR 721.1660 have been corrected.

2. Chemical substances not listed on the TSCA Inventory are no longer covered by this rule.

3. The use of C.I. Direct Red 28 (CAS No. 573–58–0) as an indicator dye and the use of benzidine-based chemical substances as an analytical standard were added to the list of uses not designated as significant new uses under this SNUR.

IV. Background Information on Benzidine-Based Chemical Substances

Based upon toxicity information on benzidine and benzidine-based dyes, the Agency is concerned that all the benzidine-based chemical substances listed in this rule may be carcinogens.

The molecule benzidine can only be isolated for commerce or use in the form of a salt. In recognition of this fact, whenever the term ''benzidine'' is used in this section of the preamble, it refers to the molecule benzidine, CAS No. 92–87–5, as well as to all benzidine salts.

Benzidine is an aromatic amine that has been used as a feedstock for production of man-made dyes since the late 1800's. Dyestuffs were among the first products of the developing chemical industry, and aromatic amines were the first synthetic chemicals found to cause cancer in humans. This was first reported in the last century, when some workers manufacturing dyes developed bladder cancer. Benzidine was subsequently found to be a potent carcinogen in humans and animals.

Several epidemiologic studies of occupationally exposed workers have demonstrated that benzidine exposure is associated with a high risk of developing bladder cancer (Ref. 1). Benzidine is classified by EPA as Group A, a human carcinogen (IRIS, 1996). Benzidine is also classified by the International Agency for Research on Cancer (IARC) as a Group 1 carcinogen, which are chemicals known to cause cancer in humans and animals (Ref. 2).

Originally, only benzidine was considered to be carcinogenic. However, studies found that dyes derived from benzidine release free benzidine via metabolic routes (Ref. 3). The dyes were predicted to be carcinogens based on these findings. Animal bioassays performed by the National Cancer Institute (NCI) in 1978 confirmed that administration of three different benzidine-based dyes each led to cancer. (Ref. 4)

EPA's hazard analysis (Ref. 5) is based on studies of tested representative benzidine-based dyes, as well as benzidine, from which they are synthesized, and to which they break down or metabolize. The overwhelming health concern for benzidine and benzidine-based dyes is for bladder cancer generally believed to be caused through any route of exposure. As of June 1974, the Occupational Safety and Health Administration (OSHA) requires that manufacture of benzidine be contained within a closed system (29 CFR 1910.1010 Benzidine). In addition, the American Conference of Governmental Industrial Hygienists (ACGIH) has classified benzidine as a ''confirmed human carcinogen'' with no Threshold Limit Value (TLV) assigned, and has recommended that ''all exposure to benzidine should be kept to an absolute minimum'' (Ref. 6).

Twelve benzidine-based dyes have been demonstrated to metabolize to benzidine in one or more of four species (Ref. 7). National Toxicology Program (NTP) cancer bioassays by the oral route in rodents using Direct Black 38 (CAS No. 1937–37–7), Direct Blue 6 (CAS No. 2602–46–2), and Direct Brown 95 (CAS No. 16071–86–6), showed statistically significantly elevated tumor incidence of the liver following oral administration. The time to tumor formation was 5 to 13 weeks. No tumors were found in the controls (Ref. 4). In response to these and other data, the National Institute for Occupational Safety and Health (NIOSH) and NCI have jointly recommended that these three dyes be handled in the workplace as if they were human carcinogens, and have suggested guidelines for minimizing employee exposure (Ref. 8).

Bioavailability studies in Rhesus monkeys, rats, and dogs revealed levels of benzidine in the urine, after the administration of the above-mentioned dyes, equivalent to the levels found after administration of a comparable volume of straight benzidine (Refs. 3 and 7). For this reason, IARC has classified these benzidine-based dyes as Group 2A chemicals, which are carcinogenic to animals and probably carcinogenic to humans (Refs. 1, 8, and 9). Given the consistent results from testing these dyes, as well as known mechanistic similarities among benzidine-based dyes, the entire class of benzidine-based dyes are expected to have a similar degree of toxicity. In addition, NIOSH has recommended that all benzidine-based dyes be recognized as potential human carcinogens, based upon the evaluation of information on the carcinogenicity and metabolism of these dyes (Ref. 10).

There are exposure issues for both the parent amines and the finished dyes. Most available exposure data are for groups of dyes, rather than for individual dyes. Inhalation, skin absorption, and ingestion are possible routes of exposure in a variety of settings where benzidine-based dyes are either manufactured or used. Benzidine and monoacetyl benzidine, a metabolite, have been found in the urine of workers making or using benzidine-based dyes in the paper, textile, leather, and dye manufacturing industries (Ref. 10). The amount of benzidine found in the urine was more than could be accounted for by only benzidine impurities in the dyes.

Exposure estimates for dyes were developed based on the result of a monitoring study conducted collaboratively by EPA and industry (Ref. 11). Using this information, and based on models from EPA and industry, exposure estimates have been calculated for those workers who weigh powder dyes in manufacturing establishments. From these estimates, EPA predicts the highest exposure would occur for workers who would manufacture benzidine-based dyes or who would weigh such dyes, and is also concerned about potential exposures to workers who would operate dyeing machinery (Ref. 11).

V. Rationale and Objectives for the Rule

To determine what would constitute a significant new use of benzidine-based chemical substances, EPA considered relevant information regarding the toxicity of the substances, likely exposure and releases associated with potential uses, and the four factors listed in TSCA section 5(a)(2). The Agency has concerns for bladder cancer in workers which is generally believed to be caused through any route of exposure to benzidine-based chemical substances (Ref. 5). EPA classified benzidine as Group A, a human carcinogen (IRIS, 1996). Benzidine has an IARC classification as a Group 1 carcinogen, which are chemicals known to cause cancer in humans and animals. IARC has also classified several benzidine-based dyes as Group 2A chemicals, which are carcinogenic to animals and probably carcinogenic to humans. The benzidine-based dyes that have not been tested are also suspected carcinogens (e.g., Ref. 10).

EPA has determined that there is no ongoing manufacture, import, or

processing, of the listed benzidine-based chemical substances, except for use in small amounts as a reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; and also for C.I. Direct Red 28 as an indicator dye. EPA believes that the use of the subject benzidine-based substances for the uses designated at § 721.1660 would result in increases in production as well as the type, form, magnitude, or duration of exposure to these known or suspected carcinogens. Therefore, EPA is designating the uses at § 721.1660 as significant new uses (Ref. 12).

Based on these considerations, EPA wishes to achieve the following objectives with regard to the significant new uses that are designated in this rule. Specifically, EPA wants to ensure that it:

1. Receives notice of any company's intent to manufacture, import, or process the benzidine-based chemical substances for the significant new uses designated in this rule before that activity begins.

2. Has an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing the listed benzidine-based chemical substances for the significant new uses designated in this rule.

3. Can regulate prospective manufacturers, importers, or processors of the listed benzidine-based chemical substances before any significant new use occurs, provided that the degree of potential health risk is sufficient to warrant such regulation.

For the preceding reasons, EPA is designating any use of the benzidine-based chemical substances listed in § 721.1660, except for those uses listed in § 721.1660(a)(2), as significant new uses.

VI. Alternatives

Before promulgating this SNUR, EPA considered alternative regulatory actions for the listed benzidine-based chemical substances. It determined that the benzidine-based chemical substances listed in this rule are currently not subject to Federal notification requirements nor are they currently subject to any other Federal rules that regulate risks to human health or the environment to a sufficient extent to justify using those regulations as an alternative to this SNUR. EPA also considered the following alternative actions.

1. *Promulgate a TSCA section 8(a) reporting rule for these chemical substances.* Under such a rule, EPA could require any person to report information to the Agency when they intend to manufacture, import, or process the listed benzidine-based chemical substances, for a significant new use as listed in this rule (15 U.S.C. 2607). However, in the case of these particular chemical substances, the use of section 8(a) rather than SNUR authority would not provide the opportunity for EPA to review human and environmental risks associated with new uses of a chemical substance and, if necessary, take immediate follow-up regulatory action under TSCA section 5(e) or section 5(f) to prohibit or limit the activity before it begins. In view of the level of health concerns for the listed benzidine-based chemical substances, the Agency believes that a section 8(a) rule for those chemical substances would not meet EPA's regulatory objectives.

2. *Regulate the listed benzidine-based chemical substances under section 6 of TSCA.* EPA may regulate under section 6 if there is a reasonable basis to conclude that the manufacture, importation, processing, distribution in commerce, use, or disposal of a chemical substance or mixture ''presents or will present'' an unreasonable risk of injury to human health or the environment. A finding of unreasonable risk indicates a determination that the reduction of health or environmental risk resulting from a potential regulation outweighs the regulatory burden to society.

In the case of this rule, EPA decided that a SNUR was more appropriate than a section 6 rule because the Agency has not determined that the ongoing uses raise sufficient concerns to justify a section 6 regulation. At the same time, EPA's concerns are for potential future uses, and the notification which is required by this SNUR will be sufficient to allow the Agency to make the decisions necessary to protect against such uses.

VII. Applicability to Uses Occurring Before Effective Date of this Final Rule

EPA believes that the intent of section 5(a)(1)(B) is best served by designating a use as a significant new use as of the proposal date of this SNUR rather than as of the effective date of this final rule. If uses begun during the proposal period of a SNUR were considered ongoing, rather than new, as of the effective date, it would be difficult for EPA to establish SNUR notice requirements, because any person could defeat the SNUR by initiating the proposed significant new use before the rule became final, arguing that the use is no longer new.

Persons who began commercial manufacture, importation, or processing of the listed benzidine-based chemical substances for any significant new use listed in this rule between issuance of the proposed rule and the effective date of this SNUR must cease that activity before the effective date of this rule. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires. If, however, persons who began commercial manufacture, importation, or processing of the chemical substances between the issuance of the proposed rule and the effective date of this SNUR meet the conditions of advance compliance as codified at § 721.45(h), those persons will be considered to have met the requirements of this final SNUR for those activities.

VIII. Response to Comments Received on Proposed Rule

The Agency received comments on the proposed rule from two businesses and two trade associations. The Agency reviewed and considered all significant comments received. These comments and EPA's responses follow:

Comment. Some of the dyes listed in the proposed rule are assigned incorrect CAS numbers and nomenclature.

Response. EPA reviewed the list of dyes in the proposed rule. Inconsistencies in naming substances were identified and corrected in table 1 in § 721.1660 of this final rule. Inaccurate CAS numbers were also identified and corrected in table 1 of this final rule for C.I. Direct Blue 2 (CAS No. 2429–73–4), C.I. Direct Brown 6 (CAS No. 2893–80–3), and C.I. Direct Brown 74 (CAS No. 8014–91–3). Additionally, chemical names were added to table 1 of this rule to futher identify substances subject to SNUR reporting. These corrections were minor in nature and did not change the types of benzidine-based dyes subject to this final SNUR.

Comment. A majority of the chemical substances listed in the proposed rule are not found on the TSCA Inventory. A SNUR for substances that are not on the TSCA Inventory is unnecessary because the ''PMN would serve the same purpose''.

Response. EPA conducted a review of the TSCA Inventory. This review revealed that 24 out of 149 benzidine-based chemical substances in the proposed SNUR were on the TSCA Inventory and the remaining substances were not. EPA has removed the substances that are not on the TSCA Inventory from the final list of

substances requiring notification of a significant new use. Those substances continue to be subject to the reporting requirements under TSCA section 5(a)(1) (15 U.S.C. 2604(a)(1)). Section 5(a)(1) requires a person who manufactures a chemical substance that is not on the Inventory, and not otherwise excluded or exempted from the requirements of section 5, to file a premanufacture notification (PMN) with EPA. When EPA proposed the SNUR it based the proposal on certain objectives that it announced in the preamble to the proposed rule (60 FR 45121, August 30, 1995). EPA has concluded that these same objectives can be met through the submission of a PMN for benzidine-based chemical substances that are not on the Inventory and requiring a SNUN in addition is not necessary.

Comment. C.I. Direct Red 28, a benzidine derivative, is used as a mineral acid indicator but was not identified in the proposed rule as an ongoing use. Also, certain uses of benzidine as an analytical laboratory standard, as with EPA Reference Method 8270, are also ongoing. These uses are similar to other ongoing uses identified in the proposed rule.

Response. EPA added the use of C.I. Direct Red 28 (CAS No. 573–58–0) as an indicator dye and the use of benzidine and benzidine-based chemical substances as an analytical standard to the list of ongoing uses based on information from commenters and EPA's Office of Solid Waste and Emergency Response (OSWER) (Benzidine SNUR Memo, 50617A). No additional ongoing uses of benzidine-based chemical substances were identified. Ongoing uses, as identified in § 721.1660(a)(2) of this final rule, are not subject to SNUR reporting. EPA decided to add these two uses because they are similar to other ongoing uses that were originally proposed. Like some of the proposed ongoing uses, the additional uses rely on benzidine-based substances to test for the presence of chemical substances. EPA received no objections to the inclusion of the original uses in this SNUR and has concluded that additional notice is not necessary to add these similar uses.

Comment. There are other benzidine-based dyes on the TSCA Inventory which were not listed in the proposed rule.

Response. EPA's intent is to require notification prior to the manufacture, import, or processing of all benzidine-based chemical substances on the TSCA Inventory for all non-ongoing uses. EPA conducted a thorough search of the TSCA Inventory which revealed that there are additional benzidine-based chemical substances on the TSCA Inventory that were not included in the proposed SNUR. EPA will propose a SNUR for these additional benzidine-based chemical substances in the near future.

Comment. EPA should exempt all laboratory uses of very small amounts of benzidine-based chemical substances from the SNUR where prudent laboratory practices are employed. Another comment suggested that the SNUR should not apply to laboratory uses of benzidine-based chemical substances.

Response. EPA agrees with the first comment and under existing EPA regulations, a person who manufacturers, imports, or processes a listed substance for a significant new use is not subject to SNUR notification requirements if the person is utilizing small quantities for research and development and meets the other safeguards as specified in 40 CFR 721.47. In addition, this SNUR will not cover identified laboratory uses which are ongoing (listed in § 721.1660(a)(2) of this rule). However, EPA does not agree with the second comment that all laboratory uses in general should be excluded. The purpose of the SNUR is to insure that EPA has an opportunity to review human and environmental risks associated with significant new uses of a chemical substance and, if necessary, take further action to protect against those risks. If EPA exempts all laboratory uses without any of the safeguards specified in 40 CFR 721.47, as suggested by the commenter, then persons may engage in those uses without further EPA review of these additional human and environmental exposures. The comment did not provide adequate information to allow EPA to determine the extent or possible consequences of these exposures. Given the potentially hazardous nature of benzidine-based chemical substances, EPA believes it is not appropriate to exempt all laboratory uses from the SNUR. Anyone who wishes to engage in such a new use in the future, however, may submit a significant new use notice and initiate the process for determining whether those uses pose an unreasonable risk.

Comment. The use of benzidine as a laboratory standard or an indicator dye does not constitute manufacturing, importing, or processing for a commercial purpose, i.e., for distribution in commerce. The analytical procedures, of which the benzidine is part, either consume the benzidine or produce by-products which are properly disposed. No benzidine is manufactured or processed in the course of these uses, nor is it for the purpose of distribution in commerce.

Response. EPA generally agrees with the commenter that a SNUR only regulates manufacturing and processing activities that are undertaken for commercial purposes; however, a laboratory could be engaging in regulated activities when it uses a listed benzidine-based chemical substance. TSCA provides that SNURs apply only to persons who ''manufacture or process'' subject substances (15 U.S.C. 2604(a)(1)(B)). TSCA also defines the term ''manufacture'' to include importation of as well as production (15 U.S.C. 2602(7)). TSCA further provides that SNURs only regulate manufacturing, importation, and processing activities if those activities are for ''commercial purposes'' (15 U.S.C. 5(I)). EPA interprets these provisions broadly to encompass a wide range of activities. TSCA and the SNUR regulations define manufacturing to include any activities associated with the production or importation of substances with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer or importer (40 CFR 720.3(r), defining ''manufacture or import for commercial purposes''). Processing for commercial purposes is also defined to encompass a wide range of activities (40 CFR 721.3, defining ''process for commercial purposes''). Based upon these regulations, a laboratory could be engaged in regulated activity when it uses a listed benzidine-based substance. Determining whether a laboratory is engaged in a regulated activity is very fact specific and requires an assessment of a variety of the circumstances surrounding the laboratory's activities. The commenter has not provided enough information for EPA to determine whether the activities it describes would be subject to the SNUR. Rather than speculate on hypothetical situations, EPA advises a laboratory that intends to engage in activities involving a significant new use of a listed benzidine-based chemical substance to contact EPA as specified in 40 CFR 721.11 to determine in advance whether it is subject to the SNUR. Additionally, as stated in the previous response to comment, under existing EPA regulations, a person who manufactures, imports, or processes a listed substance for a significant new use is not subject to SNUR notification requirements if the person is utilizing small quantities of research and development and meets the other

safeguards as specified in 40 CFR 721.47.

Comment. The SNUR will give an unfair advantage to foreign producers of benzidine-based chemical substances, and to those who import textiles dyed with such chemicals into the US.

Response. While EPA does not presently have a sufficient basis to support a regulatory action related to the import of articles manufactured with benzidine-based chemical substances, we have taken steps to address concerns with benzidine-based chemical substances on an international level. EPA has helped the Organization for Economic Cooperation and Development (OECD) organize an information clearinghouse so the OECD member countries can share information regarding the issues, concerns, and risk management activities surrounding benzidine-based chemical substances. EPA has also provided information to India through the U.S. Department of State. EPA plans to inform the OECD, United Nations (UN) International Program on Chemical Safety (IPCS) and the International Register of Potentially Toxic Chemicals (IRPTC) of the issuance of this SNUR so that this action might encourage other countries to examine the risks associated with the manufacture and use of benzidine-based chemical substances in their countries.

Comment. The SNUR is a ''complete product ban'', put into effect without ''sufficient analysis of the alternatives and input from the interested public''.

Response. EPA disagrees. A SNUR requires only that manufacturers, importers, and processors of the listed substances notify EPA at least 90 days before beginning any activity that EPA has designated as a ''significant new use.'' The advance notification required by the SNUR allows EPA to evaluate the proposed new use in more detail. If that evaluation reveals a concern, EPA can take action to prevent or limit unreasonable risk from the new use of the substance. Conversely if EPA decides not to take any further action, the activity may proceed.

EPA also disagrees with the comment that it failed to analyze alternatives or public input. The commenter failed to explain why it believed that there were other viable alternatives to a SNUR. Unit VI of this preamble includes EPA's analysis of alternative regulatory actions and other provisions of TSCA. EPA also discussed plans to issue a SNUR at several public meetings, and at a meeting with industry representatives held during in April, 1995 (Meeting Minutes on Benzidine-Based and Benzidine Congener-Based Dyes, 50617A). Additionally, the public submitted comments when this SNUR was proposed and EPA is responding to them in this preamble.

Comment. EPA has not addressed the issue of the ''actual risk posed by these chemicals in their current limited use''.

Response. Because this SNUR is not intended to subject ongoing uses of benzidine-based chemical substances to SNUR reporting requirements, EPA did not specifically assess risk posed by ongoing uses of benzidine-based chemical substances. Such an assessment would fall outside the scope of this rule and therefore, is unnecessary to support this rule.

Comment. The rule as proposed would not regulate significant new uses of an existing product, but rather would regulate ''old, established products and applications which are not currently used'' in the U.S.

Response. The statutory language of TSCA section 5, the legislative history, and underlying policy support EPA's conclusion that it has the authority to classify the resumption of manufacturing or processing of chemical substances as a ''significant new use.'' The term ''new'' generally encompasses uses that are occurring for the first time as well as uses that were discontinued and then occur again. See, e.g., Webster's II New Riverside University Dictionary, 1988.

The factors that TSCA requires the Administrator to consider before determining that a use is ''significant'' and ''new'' apply equally to first time and resumed uses. Section 5(a)(2) states that the Administrator's ''significant new use'' determination shall be made after considering all relevant factors including ''projected volume,'' increases in ''magnitude and duration of exposure,'' and the reasonably anticipated manner and methods of manufacturing, processing, distribution, and disposal. Both first time and resumed use may result in an increase in production volume and exposure to a chemical substance. Both types of uses also can lead to increased risks associated with manufacture, processing, distribution, and disposal.

Moreover, the legislative history of section 5 suggests that Congress intended that increased volume of manufacturing or processing would be subject to the requirements of that section. This adds further support to the conclusion that a resumption of manufacture, which necessarily entails an increase in production volume, may be classified as manufacture for a significant ''new'' use. See, e.g., H.R. Rep. No. 94–1679, 94th Cong., 2nd Sess. 66 (1976), Legislative History of the Toxic Substances Control Act 679; Senate Consideration of Conference Report on S. 3149, Sept. 28, 1976, Legislative History of the Toxic Substances Control Act at 723.

Comment. Thirty days is not a fair and reasonable comment period for such complex regulations, with extensive dockets.

Response. EPA disagrees that 30 days is not a fair and reasonable comment period. EPA allows a reasonable amount of time for comments based upon the complexity of the proposed rule and the record. Due to the relatively routine nature of SNURs and the limited nature of the material in the docket for this particular rule, the Agency believes that a 30-day comment period is reasonable in this case. EPA received no requests from the public for an extension of the comment period.

Comment. The Agency is not justified in setting retroactive dates as the effective dates for determining new uses.

Response. EPA disagrees and believes it is reasonable to make the effective date of the Agency's ''significant new use'' determination the proposal date of the rule rather than the date of the final rule. If EPA adopted the date of the final rule as the effective date, then a person could defeat the final rule simply by engaging in the proposed significant new use before the rule took effect. Further, the notification requirements for use of any listed benzidine-based chemical substance only take effect when the rule becomes final. This rule operates prospectively, not retroactively as the comment suggests.

Comment. EPA may be premature in ''extending its concern to the listed dye products'' due to SNUN requirements for test data, protocol consultation, and human exposure and environmental release data.

Response. EPA disagrees that issuing a SNUR is premature. Congress designed SNURs to allow EPA to obtain data about new uses of chemical substances that may pose significant concerns. This action is based on Agency concerns for all benzidine-based substances listed in the rule. Agency concerns for all these benzidine-based substances are based on existing carcinogenicity and exposure data of benzidine and benzidine-based substances.

As stated in Unit IX of the proposed rule (60 FR 45119, August 30, 1995), TSCA section 5 does not require persons to develop any particular test data before submitting a SNUN. Persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (15 U.S.C.

2604(d); 40 CFR 721.25). Further, while EPA does require the submission of test data in a submitter's possession, EPA does not require the development of test data when a SNUN is submitted. Rather, EPA suggests to potential SNUR submitters the kind of data that would permit a reasoned evaluation of potential risks posed by listed benzidine-based chemical substances for an intended use. The characterization of potential health and environmental effects will help the Agency determine if regulation of the listed SNUR substance for the intended use is warranted.

Comment. According to the July 1995 American Association of Textile Chemists and Colorists (AATCC) Buyer's Guide, 15 companies were listed as distributing benzidine dyes.

Response. Of the 15 companies identified in the 1995 AATCC Buyer's Guide as selling benzidine-based chemical substances identified in this SNUR, EPA had previously contacted nine that were listed in the 1994 AATCC Buyer's Guide prior to publication of the proposed SNUR (Phone Contacts with Benzidine Dye Manufacturers and Distributors, 50617). Representatives of those nine companies confirmed that they were not manufacturing, importing, or distributing benzidine-based chemical substances identified in this SNUR. EPA representatives attempted to contact the additional six companies newly listed in the 1995 Buyer's Guide (Buyer's Guide, 50617A). Five companies indicated to EPA that they were not manufacturing, importing, or distributing benzidine-based chemical substances. EPA representatives were unable to contact the remaining company although repeated attempts were made using the information contained in the 1995 AATCC Buyer's Guide. Thus, based on the information currently available, EPA does not believe that the benzidine-based chemical substances identified in this SNUR are in commerce at this time.

IX. Test Data and Other Information

EPA recognizes that under TSCA section 5, persons are not required to develop any particular test data before submitting a significant new use notice. Rather, persons are required only to submit test data in their possession or control and to describe any other data known to, or reasonably ascertainable by, them (15 U.S.C. 2604(d); 40 CFR 721.25).

However, in view of the potential health risks that may be posed by a significant new use of the listed benzidine-based chemical substances, EPA suggests potential SNUR notice submitters include data that would permit a reasoned evaluation of risks posed by these chemical substances when utilized for an intended use. EPA currently believes that the results of the following tests could help adequately characterize possible health and environmental effects of the chemical substances: Cancer bioassays, metabolism testing, and tests for environmental fate and ecotoxicity. However, these studies may not be the only means of identifying potential risks. SNUR notices submitted without accompanying test data may increase the likelihood that EPA would take action under TSCA section 5(e).

EPA encourages persons to consult with the Agency before submitting a SNUN for benzidine-based chemical substances. As part of this optional prenotice consultation, EPA will discuss the test data it believes necessary to evaluate a significant new use of the chemical substances and advise in the selection of a protocol for testing the chemical substances. Test data should be developed according to TSCA Good Laboratory Practice Standards at 40 CFR part 792. Failure to do so may lead EPA to find such data to be insufficient to reasonably evaluate the health or environmental effects of the chemical substances.

EPA urges SNUN submitters to provide detailed information on human exposure or environmental release that may result from the significant new use of the listed benzidine-based chemical substances. In addition, EPA encourages persons to submit information on potential benefits of the chemical substances and information on risks posed by the chemical substances compared to risks posed by potential substitutes.

X. Economic Analysis

EPA has evaluated the potential costs of establishing SNUR reporting requirements for the benzidine-based chemical substances listed in this rule (Ref. 12). While there is no precise way to calculate the total annual cost of compliance with this rule, EPA estimates that the reporting cost for submitting a SNUN ranges from $7,198 to $8,170, including a $2,500 user fee. EPA believes that there will be few, if any, SNUNs submitted. Furthermore, while the expense of a notice and the uncertainty of possible EPA regulation may discourage certain innovations, that impact would be limited because such factors are unlikely to discourage an innovation that has high potential value. The Agency's economic analysis is available in the public record for this rule (OPPTS–50617A).

XI. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPPTS–50617A). The record includes basic information considered by the Agency in developing this rule and the references listed in Unit XII of this preamble.

A public version of this record, without any Confidential Business Information is available for reviewing and copying from 12 noon to 4 p.m., Monday through Friday, except legal holidays, in the TSCA Nonconfidential Information Center (NCIC), located in Rm. NE–B607, 401 M St., SW., Washington, DC.

XII. References.

(1) International Agency for Research on Cancer (IARC). IARC Monographs 1982, 29, 295–310, 311–330, 321–330).

(2) IARC Monographs, Supplement 7:123–125 (1987).

(3) Rinde, E. and Troll, W. ''Metabolic Reduction of Benzidine Azo Dyes to Benzidine in the Rhesus Monkey.'' *Journal of the National Cancer Institute* 55:181–182 (1975).

(4) National Cancer Institute (NCI). ''13-week subchronic toxicity studies of Direct Blue 6, Direct Black 38 and Direct Brown 95 dyes.'' NCI Carcinogenesis. Technical Report Series Number 108. 127p (1978).

(5) USEPA. Chemical Screening and Risk Assessment Division. Benzidine/Benzidine Congener Dyes Support Document, Ocotber 24, 1994.

(6) ACGIH. American Conference of Government Industrial Hygienists, Inc. ''Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed.'' 121-122p (1991).

(7) Lynn, R.K. et al. ''Metabolism of bisazobiphenyl dyes derived from benzidine, 3,3'-methylbenzidine and 3,3'-dimethoxybenzidine to carconogenic aromatic amines in the dog and rat.'' *Toxicology and Applied Pharmacology* 56:248–258 (1980).

(8) NIOSH/NCI, *Current Intelligence Bulletin*, 24(1,5):7–9 (1978).

(9) IARC Monographs, Supplement 7:125–126 (1987).

(10) NIOSH, Special Occupational Hazard Review for Benzidine-Based Dyes (1980).

(11) USEPA. 1990a (April). U.S. Environmental Protection Agency. Textile Dye Weighing Monitoring Study. EPA 560/5–90–009 and Supplement 560/5–90–010.

(12) USEPA. Regulatory Impact Branch, USEPA/OPPT/EETD, June 1, 1993. ''Production, Uses, and Imports of

Benzidine Based Chemicals.'' Prepared by Meridian Research, Inc.

(13) USEPA. Regulatory Impacts Branch, Economics, Exposure, and Technology Division. ''Economic Analysis to Support the Proposed SNUR for Benzidine and Benzidine-based Dyes''. May 12, 1995.

XIII. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), it has been determined that this rule is not ''significant'' and is therefore not subject to OMB review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), EPA certifies that this rule will not have a significant impact on a substantial number of small entities. This certification can be found in the docket for this rule (OPPTS–50617A). EPA has analyzed the impact of the rule on small entities based upon the criteria in the Regulatory Flexibility Act. Unit XIII.C. of this preamble and the Economic Analysis (Ref. 13) to support this SNUR (docket number OPPTS–50617A) describe the burden and costs of compliance of this rule as well as the potential impacts on small entities.

This SNUR applies to any small or large business that may wish to engage in the significant new use described in the rule. It appears that no small or large businesses are currently engaged in activity that is the subject of this rule. Although there may be some small businesses that may decide to conduct such activities in the future, it is not possible at this time to determine for certain how many, if any, there may be. Based upon past experiences, EPA expects to receive few, if any SNUNs from either small or large businesses in response to this SNUR. To date, the Agency has received less than 10 SNUNs in response to the many SNURs promulgated by EPA in the past.

There are no existing Federal rules that may duplicate, overlap, or conflict with this rule. Finally there are no significant alternatives to this rule that minimize economic impacts on small businesses and accomplish the statutory objective of insuring that EPA has an opportunity to review and evaluate the risks associated with a new use to determine whether further regulatory activity is necessary.

Information relating to this determination may be provided to the Chief Counsel for Advocacy of the Small Business Administration upon request, and is included in the docket for this rulemaking. Any comments regarding the economic impacts that this regulatory action may impose on small entities should be submitted to the Agency at the address listed above.

C. Unfunded Mandate Reform Act

This rule is not subject to the requirements of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) because this rule does not contain regulatory requirements that might significantly or uniquely affect small governments and does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. Since no current ongoing manufacture, import, or processing of the listed benzidine-based chemical substance have been identified except for uses of such substances as a reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; or the use of C.I. Direct Red 28 as an indicator dye, this rule will not affect state, local, tribal governments, or the private sector. EPA expects to receive few, if any, SNUNs in response to this SNUR.

D. Executive Order 12898

Pursuant to Executive Order 12898 (59 FR 7629, February 16, 1994), entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, the Agency has considered environmental justice related issues with regard to the potential impacts of this action on the environmental and health conditions in low-income and minority communities and does not expect any negative impacts since no current ongoing manufacture, import, or processing of the listed benzidine-based chemical substances were identified except for uses of such substances as a reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; or the use of C.I. Direct Red 28 as an indicator dye. Additionally, EPA expects to receive few, if any, SNUNs in response to this SNUR.

E. Submission to Congress and the General Accounting Office

Under section 801(a)(1)(A) of the Administrative Procedure Act (APA) (5 U.S.C. 801) EPA submitted 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 General Accounting Office prior to publication of this rule in the Federal Register. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2) of the APA as amended.

F. Paperwork Reduction Act

The information collection requirements contained in this rule have already been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This activity falls under OMB control number 2070–0038 (EPA ICR No. 1188), which covers the submission of SNUNs related to existing chemicals. Specifically, persons subject to this SNUR must submit a SNUN to EPA at least 90 days before manufacturing, importing, or processing a chemical substance for any significant new use (15 U.S.C. 2604(a)(1)(B)). The SNUN allows EPA to review and evaluate the intended use and prohibit or limit that use if the degree of potential health risk is sufficient to warrant such regulation. Persons subject to this SNUR would comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under section 5(a)(1)(A) of TSCA (15 U.S.C.2604(a)(1)(A)).

Additionally, persons who intend to export a chemical substance identified in the final SNUR are subject to TSCA section 12(b) (U.S.C. 2611(b) and 40 CFR part 707). Persons who intend to import a chemical substance identified in the final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and to the regulations codified at 19 CFR 12.118 through 12.127 and 12.128. The EPA policy in support of import certification appears at 40 CFR part 707. OMB has already approved these activities under OMB Control No. 2070–0030 (EPA#795). EPA must withhold from disclosure trade secret or confidential financial or commercial information submitted under TSCA.

In submitting a SNUN, the public reporting burden for this collection of information is estimated to vary from 94 to 113 hours per response, with an average of 103 hours 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. These hours are included and accounted for in the above-referenced existing ICR.

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. EPA is also amending the table of currently approved information collection requests (ICR) control numbers issued by OMB for various regulations, which appears at 40 CFR part 9. This amendment updates the table to accurately display OMB approval of the information requirements contained in this final rule. The display of the OMB control number in this notice and its subsequent codification in the Code of Federal Regulations satisfies the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and OMB's implementing regulations at 5 CFR part 1320. The ICR was previously subject to public notice and comment prior to OMB approval. As a result, EPA finds that there is ''good cause'' under section 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(B)) to amend this table without additional notice and comment. Due to the technical nature of the table, further notice and comment would be unnecessary.

Send comments on the burden estimates and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to Chief, Information Policy Branch (2131), U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' The ICR number must be included in any correspondence.

List of Subjects

40 CFR Part 9

Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental Protection, Chemicals, Hazardous materials, Recordkeeping and reporting requirements, Significant new uses.

Dated: September 26, 1996.

Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR parts 9 and 721 are amended to read as follows:

PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT

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

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1321, 1326, 1330, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. Section 9.1 is amended by adding the following new entry to the table in numerical sequence to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control no.
* * *	* *
721.1660	2070–0038
* * *	* *

PART 721 —SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607 and 2625(e).

4. By adding new § 721.1660 to subpart E to read as follows:

§ 721.1660 Benzidine-based chemical substances.

(a) *Chemical substances and significant new uses subject to reporting.* (1) The benzidine-based chemical substances listed in table 1 of this section are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are any use other than as a reagent to test for hydrogen peroxide in milk; a reagent to test for hydrogen sulfate, hydrogen cyanide, and nicotine; a stain in microscopy; a reagent for detecting blood; an analytical standard; and also for Colour Index (C.I.) Direct Red 28 (Congo Red, CAS No. 573-58-0) as an indicator dye.

(b) *List of substances.* The following table 1 lists the benzidine-based chemical substances covered by this section.

Table 1.—Benzidine-Based Chemical Substances

CAS number	C.I. name	C.I. number	Chemical Name
92–87–5	Benzidine	N/A	[1,1'-Biphenyl]-4,4'-diamine
531–85–1	Benzidine • 2HCL	N/A	[1,1'-Biphenyl]-4,4'-diamine, dihydrochloride
573–58–0	C.I. Direct Red 28	22120	1-Naphthalenesulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[4-amino-, disodium salt
1937–37–7	C.I. Direct Black 38	30235	2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt
2302–97–8	C.I. Direct Red 44	22500	1-Naphthalenesulfonic acid, 8,8'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[7-hydroxy-, disodium salt
2429–73–4	C.I. Direct Blue 2	22590	2,7-Naphthalenedisulfonic acid, 5-amino-3-[[4'-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-4-hydroxy-, trisodium salt

Table 1.—Benzidine-Based Chemical Substances—Continued

CAS number	C.I. name	C.I. number	Chemical Name
2429–79–0	C.I. Direct Orange 8	22130	Benzoic acid, 5-[[4'-[(1-amino-4-sulfo-2-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
2429–81–4	C.I. Direct Brown 31	35660	Benzoic acid, 5-[[4'-[[2,6-diamino-3-[[8-hydroxy-3,6-disulfo-7-[(4-sulfo-1-naphthalenyl)azo]-2-naphthalenyl]azo]-5-methylphenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, tetrasodium salt
2429–82–5	C.I. Direct Brown 2	22311	Benzoic acid, 5-[[4'-[(7-amino-1-hydroxy-3-sulfo-2-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
2429–83–6	C.I. Direct Black 4	30245	2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diamino-5-methylphenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt
2429–84–7	C.I. Direct Red 1	22310	Benzoic acid, 5-[[4'-[(2-amino-8-hydroxy-6-sulfo-1-naphthalenyl)azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
2586–58–5	C.I. Direct Brown 1:2	30110	Benzoic acid, 5-[[4'-[[2,6-diamino-3-methyl-5-[(4-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
2602–46–2	C.I. Direct Blue 6	22610	2,7-Naphthalenedisulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[5-amino-4-hydroxy-, tetrasodium salt
2893–80–3	C.I. Direct Brown 6	30140	Benzoic acid, 5-[[4'-[[2,4-dihydroxy-3-[(4-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, disodium salt
3530–19–6	C.I. Direct Red 37	22240	1,3-Naphthalenedisulfonic acid, 8-[[4'-[(4-ethoxy phenyl)azo][1,1'-biphenyl]-4-yl]azo]-7-hydroxy-, disodium salt
3567–65–5	C.I. Acid Red 85	22245	1,3-Naphthalenedisulfonic acid, 7-hydroxy-8-[[4'-[[4-[[(4-methylphenyl)sulfonyl]oxy]phenyl] azo][1,1'-biphenyl]-4-yl]azo]-, disodium salt
3626–28–6	C.I. Direct Green 1	30280	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[[4'-[(4-hydroxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-6-(phenylazo)-, disodium salt
3811–71–0	C.I. Direct Brown 1	30045	Benzoic acid, 5-[[4'-[[2,4-diamino-5-[(4-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl] azo]-2-hydroxy-, disodium salt
4335–09–5	C.I. Direct Green 6	30295	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-6-[[4'-[(4-hydroxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-3-[(4-nitrophenyl)azo]-, disodium salt
6358–80–1	C.I. Acid Black 94	30336	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[[4'-[[4-hydroxy-2-[(2-methylphenyl) amino]phenyl]azo][1,1'-biphenyl]-4-yl]azo]-6-[(4-sulfophenyl)azo]-, trisodium salt
6360–29–8	C.I. Direct Brown 27	31725	Benzoic acid, 5-[[4'-[[4-[(4-amino-7-sulfo-1-naphthalenyl)azo]-6-sulfo-1-naphthalenyl]azo] [1,1'-biphenyl]-4-yl]azo]-2-hydroxy-, trisodium salt
6360–54–9	C.I. Direct Brown 154	30120	Benzoic acid, 5-[[4'-[[2,6-diamino-3-methyl-5-[(4-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl] azo]-2-hydroxy-3-methyl-, disodium salt
8014–91–3	C.I. Direct Brown 74	36300	Benzoic acid, 3,3'-[(3,7-disulfo-1,5-naphthalenediyl)bis[azo(6-hydroxy-3,1-phenylene)azo[6(or7)-sulfo-4,1-naphthalenediyl]azo[1,1'-biphenyl]-4,4'-diylazo]]bis[6-hydroxy-, hexasodium salt
16071–86–6	C.I. Direct Brown 95	30145	Cuprate(2-), [5-[[4'-[[2,6-dihydroxy-3-[(2-hydroxy-5-sulfophenyl)azo]phenyl]azo][1,1'-biphenyl] -4-yl]azo]-2-hydroxybenzoato(4-)]-, disodium

[FR Doc. 96–25650 Filed 10–4–96; 8:45 am]
BILLING CODE 6560–50–F

40 CFR Part 52

[CA 043–0017a; FRL–5617–4]

Approval and Promulgation of State Implementation Plans; California State Implementation Plan Revision; Kern County Air Pollution Control District; Santa Barbara County Air Pollution Control District; South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action on revisions to the California State Implementation Plan (SIP). The revisions concern rules from the Kern County Air Pollution Control District (KCAPCD), the Santa Barbara County Air Pollution Control District (SBCAPCD), and the South Coast Air Quality Management District (SCAQMD). This approval action will incorporate these rules into the Federally approved SIP. The intended effect of approving these rules is to regulate emissions of volatile organic compounds (VOCs) in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). The rules control VOC emissions from organic solvent degreasing operations, petroleum storage tank degassing, and gasoline transfer and dispensing operations. Thus, EPA is finalizing the approval of these rules into the California SIP under provisions of the CAA regarding EPA action on SIP submittals, SIPs for national primary and secondary ambient air quality standards, and plan requirements for nonattainment areas.

DATES: This action is effective on December 6, 1996 unless adverse or critical comments are received by November 6, 1996. If the effective date is delayed, a timely notice will be published in the Federal Register.

ADDRESSES: Copies of the rules and EPA's evaluation report for each rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rules are also available for inspection at the following locations:

Environmental Protection Agency, Air Docket (6102), 401 ''M'' Street, S.W., Washington, D.C. 20460.

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812.

Kern County Air Pollution Control District, 2700 ''M'' Street, Suite 290, Bakersfield, CA 93301.

Santa Barbara County Air Pollution Control District, 26 Castilian Drive, B–23, Goleta, CA 93117.

South Coast Air Quality Management District, 21865 E. Copley Drive, Diamond Bar, CA 91765–4182.

FOR FURTHER INFORMATION CONTACT: Mae Wang, Rulemaking Section (A–5–3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744–1200.

SUPPLEMENTARY INFORMATION:

Applicability

The rules being approved into the California SIP include: KCAPCD Rule 412.1, Transfer of Gasoline into Vehicle Fuel Tanks; KCAPCD Rule 410.3, Organic Solvent Degreasing Operations; KCAPCD Rule 102, Definitions; SBCAPCD Rule 343, Petroleum Storage Tank Degassing; and SCAQMD Rule 461, Gasoline Transfer and Dispensing.

Background

On March 3, 1978, EPA promulgated a list of ozone nonattainment areas under the provisions of the Clean Air Act, as amended in 1977 (1977 Act or pre-amended Act), that included the San Joaquin Valley Air Basin,[1] the South Central Coast Air Basin and the Los Angeles-South Coast Air Basin Area. 43 FR 8964, 40 CFR 81.305. These areas did not attain the ozone standard by their approved attainment dates.[2] On May 26, 1988, EPA notified the Governor of California, pursuant to section 110(a)(2) of the 1977 Act, that the KCAPCD, SBCAPCD and SCAQMD portions of the California SIP were inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA's SIP-Call). On November 15, 1990, the Clean Air Act Amendments of 1990 were enacted. Pub. L. 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q. In amended section 182(a)(2)(A) of the CAA, Congress statutorily adopted the requirement that nonattainment areas fix their deficient reasonably available control technology (RACT) rules for ozone and established a deadline of May 15, 1991 for States to submit corrections of those deficiencies.

On May 20, 1991, the San Joaquin Valley Unified Air Pollution Control District was formed. This district has authority over the San Joaquin Valley Air Basin Portion of Kern County. Thus, as of March 20, 1991, the KCAPCD has authority over only the Southeast Desert Air Basin portion of Kern County.

Section 182(a)(2)(A) applies to areas designated as nonattainment prior to enactment of the CAA amendments and classified as marginal or above as of the date of enactment. It requires such areas to adopt and correct RACT rules pursuant to pre-amended section 172(b) as interpreted in EPA's pre-amendment guidance.[3] EPA's SIP-Call used that guidance to indicate the necessary corrections for specific nonattainment areas. The South Central Coast Air Basin is classified as moderate and the Los Angeles-South Coast Air Basin Area is classified as extreme; therefore, these areas were subject to the RACT fix-up requirement and the May 15, 1991 deadline. All of Kern County is classified as serious. However, the Southeast Desert Air Basin portion of Kern County was not a pre-amendment nonattainment area and, therefore, was not designated and classified upon enactment of the amended Act.[4] For this reason, KCAPCD is not subject to the section 182(a)(2)(A) RACT fix-up requirement. The KCAPCD is, however, still subject to the requirements of EPA's SIP-Call because the SIP-Call included all of Kern County. The substantive requirements of the SIP-Call are the same as those of the statutory RACT fix-up requirement.

This document addresses EPA's direct final action for KCAPCD Rule 412.1, Transfer of Gasoline into Vehicle Fuel Tanks; KCAPCD Rule 410.3, Organic Solvent Degreasing Operations; KCAPCD Rule 102, Definitions; SBCAPCD Rule 343, Petroleum Storage

[1] At the time, Kern County was included in the San Joaquin Valley Air Basin and the Southeast Desert Air Basin. The San Joaquin Valley Air Basin was designated as nonattainment and the Southeast Desert Air Basin was designated as unclassified.

[2] The South Central Coast Air Basin and the Los Angeles- South Coast Air Basin Area received extensions of their attainment dates to December 31, 1987. Kern County's attainment date remained December 31, 1982.

[3] Among other things, the pre-amendment guidance consists of those portions of the proposed post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987); ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations, Clarification to Appendix D of November 24, 1987 Federal Register Notice'' (Blue Book) (notice of availability was published in the Federal Register on May 25, 1988); and the existing control technique guidelines (CTGs).

[4] The South Central Coast Air Basin, the Los Angeles-South Coast Air Basin Area, and the San Joaquin Valley Air Basin portion of KCAPCD retained their nonattainment designations and were classified by operation of law pursuant to section 107(d) and 181(a) upon the date of enactment of the CAA. The Southeast Desert Air Basin portion of the KCAPCD was designated nonattainment on November 6, 1991. See 56 FR 56694 (November 6, 1991).

Tank Degassing; and SCAQMD Rule 461, Gasoline Transfer and Dispensing. The State of California submitted these rules for inclusion into its SIP, and EPA found them to be complete pursuant to EPA's completeness criteria that are set forth in 40 CFR part 51 Appendix V.[5] The following table contains the dates of adoption, submittal, and completeness for each rule.

Rule No.	Adopted	Submitted	Complete
KCAPCD 412.1	11/9/92	1/11/93	3/26/93
KCAPCD 410.3	3/7/96	5/10/96	7/19/96
KCAPCD 102	3/7/96	5/10/96	7/19/96
SBCAPCD 343	12/14/93	3/29/94	6/3/94
SCAQMD 461	9/8/95	1/31/96	4/2/96

KCAPCD Rule 412.1 and SCAQMD Rule 461 control VOC emissions during gasoline transfer and dispensing operations. KCAPCD Rule 410.3 regulates organic solvent degreasing operations, and KCAPCD Rule 102 contains general definitions used in other district rules. SBCAPCD Rule 343 controls VOC emissions from the degassing of petroleum storage tanks. VOCs contribute to the production of ground level ozone and smog. These rules were originally adopted as part of district efforts to achieve the National Ambient Air Quality Standard for ozone and in response to EPA's SIP-Call. The following is EPA's evaluation and direct final action for these rules.

EPA Evaluation

In determining the approvability of a VOC rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 and part D of the CAA and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans). The EPA interpretation of these requirements, which forms the basis for today's action, appears in the various EPA policy guidance documents listed in footnote 3. Among those provisions is the requirement that a VOC rule must, at a minimum, provide for the implementation of RACT for stationary sources of VOC emissions. This requirement was carried forth from the pre-amended Act.

For the purpose of assisting State and local agencies in developing RACT rules, EPA prepared a series of Control Technique Guideline (CTG) documents. The CTGs are based on the underlying requirements of the Act and specify the presumptive norms for what is RACT for specific source categories. Under the CAA, Congress ratified EPA's use of these documents, as well as other Agency policy, for requiring States to ''fix-up'' their RACT rules. See section 182(a)(2)(A). The CTG applicable to KCAPCD Rule 410.3 is ''Control of Volatile Organic Emissions from Solvent Metal Cleaning,'' EPA–450/2–77–022, and the CTG applicable to SCAQMD Rule 461 is ''Control of Volatile Organic Compound Leaks from Gasoline Tank Trucks and Vapor Collection Systems,'' EPA 450/2–78–051. For some source categories, such as storage tank degassing and phase II vapor recovery, EPA did not publish a CTG. Therefore, there is no CTG applicable to KCAPCD Rule 412.1 or SBCAPCD Rule 343. In such cases, the District makes a determination of what controls are required to satisfy the RACT requirement, by reviewing the operations of facilities within the affected source category. In that review, the technological and economic feasibility of the proposed controls are considered. Additionally, for both CTG and non-CTG rules, the District may rely on EPA policy documents, such as the Blue Book or model rules, to ensure that the adopted VOC rules are fully enforceable and strengthen or maintain the SIP. KCAPCD Rule 412.1 was evaluated against EPA's draft model stage II rule, dated August 17, 1992. KCAPCD Rule 102 contains only definitions and is not considered a prohibitory rule, and therefore it was not evaluated for RACT requirements.

KCAPCD Rule 412.1 is an amended rule which regulates the dispensing of gasoline into motor vehicle fuel tanks.

This rule contains the following significant changes from the current SIP:

- Adds definitions, recordkeeping and testing requirements.
- Adds requirements related to equipment operation and maintenance.

KCAPCD Rule 410.3 is an amended rule controlling solvent degreasing operations. The only change to this rule involved revising the ''volatile organic compound'' definition to reference KCAPCD Rule 102.

KCAPCD Rule 102 contains definitions for terms used and referenced in other district rules. The definitions for ''exempt compounds'' and ''loading rack'' were added, and the definition for ''valley basin and desert basin'' was deleted.

SBCAPCD Rule 344 is a new rule which controls VOC emissions from the degassing of petroleum storage tanks, reservoirs, or other containers. Above-ground containers and underground tanks are subject to this rule depending upon their capacity and the vapor pressure of the stored organic liquid. The rule requires degassing emissions to be controlled by at least 90%, using one of several methods, including liquid balancing, liquid displacement, or refrigeration. Monitoring of refrigeration and carbon adsorption is required, along with records of monitoring results, vapor pressures, and degassing events.

SCAQMD Rule 461 is an amended rule that includes the following significant changes from the current SIP:

- Adds definitions, recordkeeping requirements, and test methods.
- Adds requirements for phase I and phase II equipment, initial and reverification testing, self-compliance inspection and maintenance, and completion of a training program.
- Deletes outdated compliance schedules.

EPA has evaluated the submitted rules and has determined that they are consistent with the CAA, EPA regulations, and EPA policy. Therefore, KCAPCD Rule 412.1, KCAPCD Rule 410.3, KCAPCD Rule 102, SBCAPCD Rule 343, and SCAQMD Rule 461 are being approved under section 110(k)(3) of the CAA as meeting the requirements of section 110(a) and part D.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future implementation plan. Each request for revision to the State implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

EPA is publishing this document without prior proposal because the Agency views this as a noncontroversial action and anticipates no adverse comments. However, in a separate document in this Federal Register publication, EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective December 6, 1996, unless, by November 6, 1996, adverse or critical comments are received.

If EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a proposed rule. EPA will not institute a second comment period on this action.

[5] EPA adopted the completeness criteria on February 16, 1990 (55 FR 5830) and, pursuant to section 110(k)(1)(A) of the CAA, revised the criteria on August 26, 1991 (56 FR 42216).

Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective December 6, 1996.

Regulatory Process

Unfunded Mandates

Under Sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must undertake various actions in association with proposed or final rules that include a Federal mandate that may result in estimated costs of $100 million or more to the private sector or to State, local, or tribal governments in the aggregate.

Through submission of this State implementation plan or plan revision, the State and any affected local or tribal governments have elected to adopt the program provided for under part D of the Clean Air Act. These rules may bind State, local, and tribal governments to perform certain actions and also require the private sector to perform certain duties. The rules being approved by this action will impose no new requirements because affected sources are already subject to these regulations under State law. Therefore, no additional costs to State, local, or tribal governments or to the private sector result from this action. EPA has also determined that this direct final action does not include a mandate that may result in estimated costs of $100 million or more to State, local, or tribal governments in the aggregate or to the private sector.

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted 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 General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Small Businesses

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et seq., EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under sections 110 and 301(a) and subchapter I, part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the CAA, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of State action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. E.P.A.*, 427 U.S. 246, 256–66 (S. Ct. 1976); 42 U.S.C. 7410(a)(2).

This action has been classified as a Table 3 action for signature by the Regional Administrator under procedures published in the Federal Register on January 19, 1989 (54 FR 2214–2225), as revised by a July 10, 1995 memorandum from Mary Nichols, Assistant Administrator for Air and Radiation. The Office of Management and Budget has exempted this regulatory action from Executive Order 12866 review.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Note: Incorporation by reference of the State Implementation Plan for the State of California was approved by the Director of the Federal Register on July 1, 1982.

Dated: September 17, 1996.

Felicia Marcus,

Regional Administrator.

Subpart F of part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart F—California

2. Section 52.220 is amended by adding paragraphs (c)(191)(i)(D), (c)(196)(i)(C)(*3*), (c)(229)(i)(A), and (c)(231)(i)(B) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(191) * * *

(i) * * *

(D) Kern County Air Pollution Control District.

(*1*) Rule 412.1, adopted on November 9, 1992.

* * * * *

(196) * * *

(i) * * *

(C) * * *

(*3*) Rule 343, adopted on December 14, 1993.

* * * * *

(229) New and amended regulations for the following APCDs were submitted on January 31, 1996, by the Governor's designee.

(i) Incorporation by reference.

(A) South Coast Air Quality Management District.

(*1*) Rule 461, adopted on September 8, 1995.

* * * * *

(231) * * *

(i) * * *

(B) Kern County Air Pollution Control District.

(*1*) Rule 102 and Rule 410.3, adopted on March 7, 1996.

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[FR Doc. 96–25467 Filed 10–4–96; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1003

45 CFR Part 79

RIN 0991–AA

Medicare and State Health Care Programs and Program Fraud Civil Remedies: Fraud and Abuse; Civil Money Penalties Inflation Adjustments

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Final rule.

SUMMARY: In accordance with Federal Civil Monetary Penalty Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, this final rule incorporates the penalty inflation adjustments for the civil money penalties for health case fraud and abuse. These inflation adjustment calculations are not applicable to those civil money penalties contained in the Social Security Act, which are exempted from this adjustment.

EFFECTIVE DATE: This rule is effective on November 6, 1996.

FOR FURTHER INFORMATION CONTACT:

Joel J. Schaer, Office of Management and Policy, (202) 619–0089.

SUPPLEMENTARY INFORMATION:

I. The Debt Collection Improvement Act of 1996

In an effort to maintain the remedial impact of civil money penalties (MPSs) and promote compliance with the law, the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–410) was amended by the Debt Collection Improvement Act of 1996 (Pub.L. 104–134) to require Federal agencies to regularly adjust certain CMPs for inflation. As amended, the law requires each agency to make an initial inflationary adjustment for all applicable CMPs, and to make further adjustments at least once every four years thereafter for these penalty amounts.

The Debt Collection Improvement Act of 1996 further stipulates that any resulting increases in a CMP due to the calculated inflation adjustments (i) should apply only to the violations that occur after October 23, 1996—the Act's effective date—and (ii) should not exceed 10 percent of the penalty indicated. In addition to those penalties that fall under the Internal Revenue Code of 1986, the Tariff Act of 1930 and the Occupational Safety and Health Act of 1970, CMPs that come under the Social Security Act are specifically exempt from the requirements of this Act.

Method of calculation

Under the Act, the inflation adjustment for each applicable CMP is determined by increasing the maximum CMP amount per violation by the cost-of-living adjustment. The ''cost-of-living'' adjustment is defined as the percentage of each CMP by which the Consumer Price Index (CPI) for the month of June of the calendar year in which the amount of the CMP was last set or adjusted in accordance with the law. Any calculated increase under this adjustment is subject to a specific rounding formula set forth in the Act.

II. OIG Civil Money Penalties Affected by this Adjustment

While the vast majority of penalty sanctions delegated to the OIG derive from CMP authorities set forth under the Social Security Act, and therefore are exempt from these inflation adjustment calculations, there are several penalty authorities, within our jurisdiction, as described below, for which adjustments are required and are now being made.

The Health Care Quality Improvement Act of 1986

In 1986, sections 421(c) and 427(b)(2) of the Health Care Quality Improvement Act (HCQIA) of 1986 (Title IV of Pub. L. 99–660) established OIG CMP authorities for failure to report medical malpractice payment information to the National Practitioner Data Bank, and for breaching the confidentiality of information reported to the Data Bank established to collect and disseminate such information. To assure the timely collection and reporting of medical malpractice payments to the Data Bank, the final regulations—published in the Federal Register (56 FR 28492, June 21, 1991) and codified at 42 CFR part 1003—set forth a CMP of up to 410,000 against any person or entity that fails to report each such payment in a timely and complete manner.

In addition, to protect the confidentiality of information reported to the Data Bank under these provisions, the final regulations also established a CMP of up to $10,000 against any person or entity who improperly discloses information reported to the Data Bank.

Based on the penalty amount inflation factor calculation, derived from dividing the June 1995 CPI by the CPI from June 1986, after rounding and the 10 percent maximum ceiling, we are adjusting the maximum penalty amount for the two CMPs under the HCQIA to $11,000 per violation.

The Program Fraud Civil Remedies Act of 1986

In 1986, sections 6103 and 6104 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–501) set forth the Program Fraud Civil Remedies Act (PFCRA) of 1986. Specifically, this authority established a CMP and an assessment against any individual who—with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim or statement to the Department. The Department's regulations—published in the Federal Register (53 FR 11656, April 8, 1988) and codified at 45 CFR part 79—set forth a CMP of up to $5,000 for each false claim or statement made to the Department.

Based on the penalty amount inflation factor calculation, derived from dividing the June 1995 CPI by the CPI from June 1986, after rounding and the 10 percent maximum ceiling, we are adjusting the maximum penalty amount for this CMP to $5,500 per violation.

III. Waiver of Proposed Rulemaking

In developing this final rule, we are waiving the usual notice of proposed rulemaking and public comment procedures set forth in the Administrative Procedure Act (APA) (5 U.S.C. 553). The APA provides an exception to the notice and comment procedures when an agency finds there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary or contrary to the public interest. We have determined that under 5 U.S.C. 553(b)(3)(B) good cause exists for dispensing with the notice of proposed rulemaking and public comment procedures for this rule. Specifically, this rulemaking comports and is consistent with the statutory authority set forth in the Debt Collection Improvement Act of 1996, with no issues of policy discretion. Accordingly, we believe that opportunity for prior comment is unnecessary and contrary to the public interest, and are issuing these revised regulations as a final rule that will apply to all future cases under this authority.

IV. Regulatory Impact Statement

Executive Order 12866

The Office of Management and Budget (OMB) has reviewed this final rule in accordance with the provisions of Executive Order 12866, and has determined that it does not meet the criteria for a significant regulatory action. As indicated above, the provisions contained in this final rulemaking set forth the inflation adjustments in compliance with the Debt Collection Improvement Act of 1996 for specific applicable civil money penalties under the authority of the OIG. The great majority of individuals, organizations and entities addressed through these regulations do not engage in such prohibited activities and practices, and as a result, we believe that any aggregate economic impact of these revised regulations will be minimal, affecting only those limited few who may engage in prohibited behavior in violation of the statutes. As such, this final rule and the inflation adjustment contained therein should have no effect on Federal or State expenditures.

Regulatory Flexibility Act

In addition, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (5 U.S.C. 601–612), unless the Secretarty certifies that a regulation will not have a significant economic impact on a substantial number of small business entities. While some penalties may have an impact on small entities, it is the nature

of the violation and not the size of the entity that will result in an action by the OIG, and the aggregate economic impact of this rulemaking on small business entities should be minimal, affecting only those few who have chosen to engage in prohibited arrangements and schemes in violation of statutory intent. Therefore, we have concluded, and the Secretary certifies, that this final rule will not have a significant economic impact on a number of small business entities, and that a regulatory flexibility analysis is not required for this rulemaking.

Paperwork Reduction Act

This final rule imposes no new reporting or recordkeeping requirements necessitating clearance by OMB.

List of Subjects

42 CFR Part 1003

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Penalties.

45 CFR Part 79

Administrative practice and procedure, Fraud, Investigations, Organizations and functions, (Governmental agencies), Penalties.

Accordingly, 42 CFR part 1003 and 45 CFR part 79 are amended as set forth below:

A. TITLE 42—PUBLIC HEALTH

CHAPTER V—OFFICE OF INSPECTOR GENERAL—HEALTH CARE; DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR part 1003 is amended as set forth below:

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

1. The authority citation for past 1003 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7, 1230a-7a, 1320b-10, 1395u(j), 1395u(k), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c) and 11137(b)(2).

2. Section 1003.103 is amended by revising paragraph (c) to read as follows:

§ 1003.103 Amount of penalty.

* * * * *

(c) The OIG may impose a penalty of not more than $11,000 [1] for each payment for which there was a failure to report required information in accordance with § 1003.102(b)(5), or for each improper disclosure, use or access to information that is subject to a determination under § 1003.102(b)(6).

* * * * *

B. TITLE 45—PUBLIC WELFARE

Subtitle A—Department of Health and Human Services, General Administration

45 CFR part 79 is amended as set forth below:

PART 79—PROGRAM FRAUD CIVIL REMEDIES

1. The authority citation for part 79 is revised to read as follows:

Authority: 31 U.S.C. 3801–3812.

2. Section 79.3 is amended by revising paragraphs (a)(1) and (b)(1) to read as follows:

§ 79.3 Basis for civil penalties and assessments.

(a) *Claims*. (1) Except as provided in paragraph (c) of this section, any person who makes a claim that the person knows or has reason to know—

(i) Is false, fictitious, or fraudulent;

(ii) Includes, or is supported by, any written statement which asserts a material fact which is false, fictitious, or fraudulent;

(iii) Includes, or is supported by, any written statement that—

(A) Omits a material fact;

(B) Is false, fictitious, or fraudulent as a result of such omission; and

(C) Is a statement in which the person making such statement has a duty to include such material fact; or

(iv) Is for payment for the provision of property or services which the person has not provided as claimed, shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than $5,500 [1] for each such claim.

* * * * *

(b) *Statements*. (1) Except as provided in paragraph (c) of this section, any person who makes a written statement that—

(i) The person knows or has reason to know—

(A) Asserts a material fact which is false, factitious, or fraudulent; or

(B) Is false, factitious, or fraudulent because it omits a material fact that the person making the statement has a duty to include in such statement; and

(ii) Contains, or is accompanied by, an express certification or affirmation of the truthfulness and accuracy of the contents of the statement, shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than $5,500 [2] for each such statement.

* * * * *

Dated: September 11, 1996.

June Gibbs Brown,

Inspector General.

Approved: September 17, 1996.

Donna E. Shalala,

Secretary.

[FR Doc. 96–25256 Filed 10–4–96; 8:45 a.m.]

BILLING CODE 4150–04–M

[1] As adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104–134).

[1] As adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104–143).

[2] As adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Debt Collection Improvement Act of 1996 (Pub. L 104–143).

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2, 25 and 90

[ET Docket No. 96–20; FCC 96–377]

Fixed Satellite Service 13.75 to 14.0 GHz Band

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission has allocated the 13.75–14.0 GHz band to the fixed-satellite service (''FSS'') on a co-primary basis for Earth-to-space (''uplink'') transmissions and has made conforming revisions to the associated service rules in Parts 25 and 90. The Commission found a growing demand for FSS in the Ku-band portion of the spectrum and concluded that this allocation will further the competitiveness of U.S. satellite operators in domestic and international markets and will provide more open and competitive markets for consumers. Further the allocation will permit added flexibility to FSS operators in the design of their systems by facilitating the co-location of additional satellites that use different frequency bands. The Commission believes that this allocation will complement and allow for greater use of the existing FSS downlink spectrum allocation.

EFFECTIVE DATE: November 6, 1996.

FOR FURTHER INFORMATION CONTACT: Tom Mooring, Office of Engineering and Technology, (202) 418–2450.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order*, ET Docket No. 96–20, FCC 96–377, adopted September 12, 1996,

and released September 26, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, N.W., Washington, D.C., and also may be purchased from the Commission's duplication contractor, International Transcription Service, (202) 857–3800, 2100 M Street, N.W., Suite 140, Washington D.C. 20037.

Summary of the Report and Order

1. By this action, the Commission amended Part 2 of its Rules to allocate the 13.75–14.0 GHz band to the FSS on a co-primary basis for uplink transmissions and made conforming revisions to the associated service rules in Parts 25 and 90. The FSS is a radiocommunication service between earth stations at a specified fixed point or between any fixed point within specified areas and one or more satellites.

2. The Commission's action is based on the growing demand for FSS in the Ku-band portion of the spectrum. For example, over 100 satellite systems are planned worldwide that would make use of the 13.75–14.0 GHz band. The locations of some of these systems are particularly well-suited for the provision of service to and from the United States. This allocation, the Commission believes, would complement and allow for greater use of the existing FSS downlink spectrum allocation. The Commission also believes that the growing international and domestic demand for FSS services should be accommodated by making this spectrum available for such operations. The Commission stated that this allocation would further the competitiveness of U.S. satellite operators in domestic and international markets and would provide more open and competitive markets for consumers.

3. In addition, the FCC adopted domestically the international footnotes that specify the spectrum sharing criteria between incumbent services and the FSS in this band, as contained in the Final Acts of the 1995 World Radiocommunication Conference. Since the 13.75–14.0 GHz band is shared with Federal Government operations, all FSS applications that request the use of any frequencies in the 13.75–14.0 GHz band are subject to the standard process whereby the Commission coordinates such applications with the National Telecommunications and Information Administration to ensure that interference to primary Government operations is minimized. The FCC also adopted a United States footnote that requires that all FSS applications requesting the use of any frequency in the 13.75–13.80 GHz band segment be coordinated on a case-by-case basis in order to minimize harmful interference to the forward space-to-space link of NASA's Tracking and Data Relay Satellite System when this link is operated in its wideband mode. This action is generally consistent with the international allocation for this band made at the 1992 World Administrative Radio Conference and will provide incumbent primary operations in this band with adequate interference protection from FSS uplinks.

4. On a related issue, the Commission declined to consider a request to eliminate the prohibition on the use of the 10.95–11.2 and 11.45–11.7 GHz FSS downlink bands by domestic systems, ruling that this issue is outside the scope of this proceeding.

Final Regulatory Flexibility Analysis

5. As required by Section 603 of the Regulatory Flexibility Act, 5 U.S.C. 603 (''RFA''), an Initial Regulatory Flexibility Analysis (''IRFA'') was incorporated into the *NPRM* in ET Docket No. 96–20.[1] The Commission sought written public comments on the proposals in the *NPRM*, including the IRFA. The Commission's Final Regulatory Flexibility Analysis (''FRFA'') in this *Report and Order* conforms to the RFA, as amended by the Contract With America Advancement Act of 1996 (CWAAA), Public Law No. 104–121, 110 Stat. 847 (1996).[2]

Need For and Objective Of the Rules

6. Our objective is to accommodate growing demand for fixed satellite services and to provide satellite operators with increased flexibility in the design of their systems. This action will allocate an additional 250 megahertz of uplink spectrum to the fixed-satellite service, which we hope will open markets and increase competition in the fixed-satellite service for both domestic and international operations.

Summary of Issues Raised by the Public Comments in Response to the IRFA

7. No comments were submitted in direct response to the IRFA. We also reviewed the general comments for potential impact on small business, and no issues were raised.

Description and Estimate of Small Entities Subject to Which Rules Will Apply

8. The Commission has not developed a definition of small entities applicable to FSS licensees. Therefore, the applicable definition of small entity is the definition under the Small Business Administration (SBA) rules applicable to Communications Services, Not Elsewhere Classified. This definition provides that a small entity is expressed as one with $11.0 million or less in annual receipts.[3] At present there are no FSS satellite licensees in the 13.75–14.0 GHz band, and therefore, there are no small businesses currently using this band. However, we acknowledge that there may be future development of new satellite systems in this frequency band that may qualify as small entities pursuant to the SBA's definition.

9. This rule may also affect satellite communications equipment manufacturers. According to the SBA's regulations, a satellite communications equipment manufacturer must have 750 or fewer employees in order to qualify as a small business concern.[4] Census Bureau data indicates that there are 858 U.S. companies that manufacture radio and television broadcasting and communications equipment, and that 778 of these firms have fewer than 750 employees and would be classified as small entities.[5] The Census Bureau category is very broad, and specific figures are not available as to how many of these firms are manufacturers of satellite communications equipment; however, we acknowledge the likelihood that some of them may qualify as small entities.

Projected Reporting, Recordkeeping and Other Compliance Requirements of the Rules

10. The antennas that will use the 13.75–14.0 GHz band must have a minimum diameter of 4.5 meters. The e.i.r.p. from a earth station using the 13.75–14.0 GHz band must be at least 68 dBW and must not exceed 85 dBW, except in the frequency band 13.772–13.778 GHz, where the e.i.r.p. must be at least 68 dBW and must not exceed 71 dBW per 6 MHz. These rules are designed to ensure that FSS uplink operations will not cause harmful interference to the incumbent users of the band. These technical rules will generally effect only those small entities

[1] See 11 FCC Rcd 5923 (1996).

[2] Subtitle II of the CWAAA is ''The Small Business Regulatory Enforcement Fairness Act of 1996'' (SBREFA), codified at 5 U.S.C. 601 *et seq.*

[3] 13 CFR 121.201, Standard Industrial Classification (SIC) Code 4899.

[4] 13 CFR 121.201, (SIC) Code 3663.

[5] U.S. Dept. of Commerce, *1992 Census of Transportation, Communications and Utilities* (issued May 1995), SIC category 3663.

that manufacture earth station uplink equipment. Such equipment must comply with the requirement of Part 25 of the Commission's Rules, 47 CFR Part 25. The types of professional engineering skills needed to assure such compliance would be available at any manufacturer of such equipment. In addition, the operators of the equipment must monitor the output power of the transmitter in order to ensure that the e.i.r.p. range is maintained. The types of professional skills needed to monitor the output power would be integral to the running of the system.

Steps Taken To Minimize Significant Economic Impact on Small Entities Consistent With Stated Objectives

11. The Commission considered and rejected an alternative proposal to restrict this FSS allocation to international service only. In this *Report and Order,* we decline to restrict the use of the 13.75–14.0 GHz band to international systems only. We believe that, by treating all U.S.-licensed geostationary fixed-satellite operations in this band under the same regulatory scheme, we will better encourage the opening of markets and the intensification of competition in the fixed-satellite services for both domestic and international operations. Further, we believe that restriction of this band to international operations only is not technically justified and would needlessly impair businesses' ability, including small businesses, to meet their customers' needs. Accordingly, we are making the 13.75–14.0 GHz band available for use by both domestic and international FSS systems.

Report to Congress

12. The Commission shall send a copy of this Final Regulatory Flexibility Analysis, along with this Report and Order, in a report to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. § 801(a)(1)(A).

List of Subjects

47 CFR Part 2

Communications equipment, Radio.

47 CFR Part 25

Communications equipment, Radio, Satellites.

47 CFR Part 90

Communications equipment, Radio.

Federal Communications Commission.

Shirley S. Suggs,
Chief, Publications Branch.

Rule Changes

Parts 2, 25 and 90 of Title 47 of the Code of Federal Regulations, are amended as follows:

PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

1. The authority citation for Part 2 continues to read as follows:

Authority: Sec. 4, 302, 303, and 307 of the Communications Act of 1934, as amended, 47 U.S.C. Sections 154, 302, 303 and 307, unless otherwise noted.

2. Section 2.106, the Table of Frequency Allocations, is amended as follows:

a. Remove the existing entries for 10.7–11.7 GHz and 12.75–13.25 GHz through 14.47–14.50 GHz.

b. Add entries in numerical order for 10.7–11.7 GHz and 12.75–13.25 GHz through 14.47–14.5 GHz.

c. Remove international footnotes 835, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861 and 862.

d. Add a note, a heading I., and international footnotes S5.149, S5.333, S5.441, S5.484 , S5.497, S5.498, S5.499, S5.500, S5.501, S5.502, S5.503, S5.503A, S5.504, S5.505, S5.506, S5.508 and S5.509 immediately following the centerheading ''INTERNATIONAL FOOTNOTES.''

e. Add a heading II. immediately preceding international footnote 444.

f. Revise United States footnote US110.

g. Remove United States footnote US287.

h. Add United States footnote US337 in numerical order.

The revisions and additions read as follows:

§ 2.106 Table of Frequency Allocations.

* * * * *

International table			United States table		FCC use designators	
Region 1—allocation GHz	Region 2—allocation GHz	Region 3—allocation GHz	Government	Non-Government	Rule part(s)	Special-use frequencies
			Allocation GHz	Allocation GHz		
*	*	*	*	*	*	*
10.7–11.7 FIXED FIXED-SATELLITE (space-to-Earth) (Earth-to-space) S5.441 S5.484 MOBILE except aeronautical mobile	10.7–11.7 FIXED FIXED-SATELLITE (space-to-Earth) S5.441 MOBILE except aeronautical mobile	10.7–11.7 FIXED FIXED-SATELLITE (space-to-Earth) S5.441 MOBILE except aeronautical mobile	10.7–11.7 US211	10.7–11.7 FIXED FIXED-SATELLITE (space-to-Earth) S5.441 US211 NG104 NG41	FIXED MICROWAVE (101) SATELLITE COMMUNICATIONS (25)	
*	*	*	*	*	*	*
12.75–13.25 FIXED FIXED-SATELLITE (Earth-to-space) S5.441 MOBILE Space Research (deep space) (space-to-Earth)	12.75–13.25 FIXED FIXED-SATELLITE (Earth-to-space) S5.441 MOBILE Space Research (deep space) (space-to-Earth)	12.75–13.25 FIXED FIXED-SATELLITE (Earth-to-space) S5.441 MOBILE Space Research (deep space) (space-to-Earth)	12.75–13.25 US251	12.75–13.25 FIXED FIXED-SATELLITE (Earth-tospace) S5.441 NG104 MOBILE US251 NG53 NG118	AUXILIARY BROADCASTING (74) CABLE TV RELAY (78) FIXED MICROWAVE (101)	

International table			United States table		FCC use designators	
Region 1—allocation GHz	Region 2—allocation GHz	Region 3—allocation GHz	Government Allocation GHz	Non-Government Allocation GHz	Rule part(s)	Special-use frequencies
13.25–13.4 AERONAUTICAL RADIONAVIGATION S5.497 S5.498	13.25–13.4 AERONAUTICAL RADIONAVIGATION S5.497 S5.498	13.25–13.4 AERONAUTICAL RADIONAVIGATION S5.497 S5.498 S5.499	13.25–13.4 AERONAUTICAL RADIONAVIGATION S5.497 Space Research (Earth-to-space)	13.25–13.4 AERONAUTICAL RADIONAVIGATION S5.497 Space Research (Earth-to-space)	AVIATION (87)	
13.4–13.75 RADIOLOCATION Standard Frequency and Time Signal-Satellite (Earth-to-space) Space Research S5.333 S5.500 S5.501	13.4–13.75 RADIOLOCATION Standard Frequency and Time Signal-Satellite (Earth-to-space) Space Research S5.333	13.4–13.75 RADIOLOCATION Standard Frequency and Time Signal-Satellite (Earth-to-space) Space Research S5.333 S5.499 S5.500 S5.501	13.4–13.75 RADIOLOCATION US110 G59 Standard Frequency and Time Signal-Satellite (Earth-to-space) Space Research S5.333	13.4–13.75 Radiolocation US110 Standard Frequency and Time Signal-Satellite (Earth-to-space) Space Research S5.333	Private Land Mobile (90)	
13.75–14.0 FIXED-SATELLITE (Earth-to-space) RADIOLOCATION Standard Frequency and Time Signal-Satellite (Earth-to-space) Space Research S5.333 S5.500 S5.501 S5.502 S5.503 S5.503A	13.75–14.0 FIXED-SATELLITE (Earth-to-space) RADIOLOCATION Standard Frequency and Time Signal-Satellite (Earth-to-space) Space Research S5.333 S5.502 S5.503 S5.503A	13.75–14.0 FIXED-SATELLITE (Earth-to-space) RADIOLOCATION Standard Frequency and Time Signal-Satellite (Earth-to-space) Space Research S5.333 S5.499 S5.500 S5.501 S5.502 S5.503 S5.503A	13.75–14.0 RADIOLOCATION US110 G59 Standard Frequency and Time Signal-Satellite (Earth-to-space) Space Research US337 S5.333 S5.502 S5.503 S5.503A	13.75–14.0 FIXED-SATELLITE (Earth-to-space) US337 Radiolocation US110 Standard Frequency and Time Signal-Satellite (Earth-to-space) Space Research S5.333 S5.502 S5.503 S5.503A	SATELLITE COMMUNICATION (25) Private Land Mobile (90)	
14.0–14.2 FIXED-SATELLITE (Earth-to-space) S5.506 RADIONAVIGATION S5.504 Land Mobile-Satellite (Earth-to-space) Space Research S5.505	14.0–14.2 FIXED-SATELLITE (Earth-to-space) S5.506 RADIONAVIGATION S5.504 Land Mobile-Satellite (Earth-to-space) Space Research	14.0–14.2 FIXED-SATELLITE (Earth-to-space) S5.506 RADIONAVIGATION S5.504 Land Mobile-Satellite (Earth-to-space) Space Research S5.505	14.0–14.2 RADIONAVIGATION US292 Space Research	14.0–14.2 FIXED-SATELLITE (Earth-to-space) RADIONAVIGATION US292 Land Mobile-Satellite (Earth-to-space) Space Research	SATELLITE COMMUNICATIONS (25) Aviation (87) Maritime (80)	
14.2–14.25 FIXED-SATELLITE (Earth-to-space) S5.506 RADIONAVIGATION S5.504 Land Mobile-Satellite (Earth-to-space) Space Research S5.505	14.2–14.25 FIXED-SATELLITE (Earth-to-space) S5.506 RADIONAVIGATION S5.504 Land Mobile-Satellite (Earth-to-space) Space Research	14.2–14.25 FIXED-SATELLITE (Earth-to-space) S5.506 RADIONAVIGATION S5.504 Land Mobile-Satellite (Earth-to-space) Space Research S5.505	14.2–14.25	14.2–14.25 FIXED-SATELLITE (Earth-to-space) Land Mobile-Satellite (Earth-to-space) Mobile except aeronautical mobile	SATELLITE COMMUNICATIONS (25) Fixed Microwave (101)	

International table			United States table		FCC use designators	
Region 1—allocation GHz	Region 2—allocation GHz	Region 3—allocation GHz	Government Allocation GHz	Non-Government Allocation GHz	Rule part(s)	Special-use frequencies
14.25–14.3 FIXED-SATELLITE (Earth-to-space) S5.506 RADIONAVIGATION S5.504 Land Mobile-Satellite (Earth-to-space) Space Research S5.505 S5.508	14.25–14.3 FIXED-SATELLITE (Earth-to-space) S5.506 RADIONAVIGATION S5.504 Land Mobile-Satellite (Earth-to-space) Space Research	14.25–14.3 FIXED-SATELLITE (Earth-to-space) S5.506 RADIONAVIGATION S5.504 Land Mobile-Satellite (Earth-to-space) Space Research S5.505 S5.509	14.25–14.3	14.25–14.3 FIXED-SATELLITE (Earth-to-space) Land Mobile-Satellite (Earth-to-space) Mobile except aeronautical mobile	SATELLITE COMMUNICATIONS (25) Fixed Microwave (101)	
14.3–14.4 FIXED FIXED-SATELLITE (Earth-to-space) S5.506 MOBILE except aeronautical mobile Land Mobile-Satellite (Earth-to-space) Radionavigation-Satellite	14.3–14.4 FIXED-SATELLITE (Earth-to-space) S5.506 Land Mobile-Satellite (Earth-to-space) Radionavigation-Satellite	14.3–14.4 FIXED FIXED-SATELLITE (Earth-to-space) S5.506 MOBILE except aeronautical mobile Land Mobile-Satellite (Earth-to-space) Radionavigation-Satellite	14.3–14.4	14.3–14.4 FIXED-SATELLITE (Earth-to-space) Land Mobile-Satellite (Earth-to-space) Mobile except aeronautical mobile	SATELLITE COMMUNICATIONS (25) Fixed Microwave (101)	
14.4–14.47 FIXED FIXED-SATELLITE (Earth-to-space) S5.506 MOBILE except aeronautical mobile Land Mobile-Satellite (Earth-to-space) Space Research (space-to-Earth)	14.4–14.47 FIXED FIXED-SATELLITE (Earth-to-space) S5.506 MOBILE except aeronautical mobile Land Mobile-Satellite (Earth-to-space) Space Research (space-to-Earth)	14.4–14.47 FIXED FIXED-SATELLITE (Earth-to-space) S5.506 MOBILE except aeronautical mobile Land Mobile-Satellite (Earth-to-space) Space Research (space-to-Earth)	14.4–14.47 Fixed Mobile	14.4–14.47 FIXED-SATELLITE (Earth-to-space) Land Mobile-Satellite (Earth-to-space)	SATELLITE COMMUNICATIONS (25)	
14.47–14.5 FIXED FIXED-SATELLITE (Earth-to-space) S5.506 MOBILE except aeronautical mobile Land Mobile-Satellite (Earth-to-space) Radio Astronomy S5.149	14.47–14.5 FIXED FIXED-SATELLITE (Earth-to-space) S5.506 MOBILE except aeronautical mobile Land Mobile-Satellite (Earth-to-space) Radio Astronomy S5.149	14.47–14.5 FIXED FIXED-SATELLITE (Earth-to-space) S5.506 MOBILE except aeronautical mobile Land Mobile-Satellite (Earth-to-space) Radio Astronomy S5.149	14.47–14.5 Fixed Mobile S5.149 US203	14.47–14.5 FIXED-SATELLITE (Earth-to-space) Land Mobile-Satellite (Earth-to-space) S5.149 US203	SATELLITE COMMUNICATIONS (25)	
*	*	*	*	*	*	*

International Footnotes

Note: The International Telecommunication Union is transitioning to new Simplified Radio Regulations. As part of the Simplified Radio Regulations, the ''S'' numbering scheme is used for international footnotes. Until such time as the Commission revises the entire list of international footnotes to comport with the new ''S'' numbering scheme, the international footnotes that are adopted in individual proceeding shall be listed in I. prior to the listing of international footnotes employing the old numbering scheme. Footnotes employing the old numbering scheme will appear in II. and shall not be deleted until all frequency bands listed within a footnote have been updated to the new ''S'' numbering scheme.

I. New ''S'' Numbering Scheme

S5.149 In making assignments to stations of other services to which the bands:
13360–13410 kHz,
25550–25670 kHz,
37.5–38.25 MHz,
73–74.6 MHz in
Regions 1 and 3,
79.75–80.25 MHz in
Region 3,
150.05–153 MHz in
Region 1,
322–328.6 MHz*,
406.1–410 MHz,
608–614 MHz in
3345.8–3352.5 MHz*,

4825–4835 MHz*,
4950–4990 MHz,
4990–5000 MHz,
6650–6675.2 MHz*,
10.6–10.68 GHz,
14.47–14.5 GHz*,
22.01–22.21 GHz*,
22.21–22.5 GHz,
22.81–22.86 GHz*,
23.07–23.12 GHz*,
31.2–31.3 GHz,
72.77–72.91 GHz*,
93.07–93.27 GHz*,
97.88–98.08 GHz*,
140.69–140.98 GHz*,
144.68–144.98 GHz*,
145.45–145.75 GHz*,
146.82–147.12 GHz*,
150–151 GHz*,
174.42–175.02 GHz*,
177–177.4 GHz*,
178.2–178.6 GHz*,
181–181.46 GHz*,

Regions 1 and 3,

1330–1400 MHz*,
1610.6–1613.8 MHz*,
1660–1670 MHz,
1718.8–1722.2 MHz*,
2655–2690 MHz,
3260–3267 MHz*,
3332–3339 MHz*,
31.5–31.8 GHz in

Regions 1 and 3,

36.43–36.5 GHz*,
42.5–43.5 GHz,
42.77–42.87 GHz*,
43.07–43.17 GHz*,
43.37–43.47 GHz*,
48.94–49.04 GHz*,
186.2–186.6 GHz*,
250–251 GHz*,
257.5–258 GHz*,
261–265 GHz,
262.24–262.76 GHz*,
265–275 GHz,
265.64–266.16 GHz*,
267.34–267.86 GHz*,
271.74–272.26 GHz*

are allocated (* indicates radio astronomy use for spectral line observations), administrations are urged to take all practicable steps to protect the radio astronomy service from harmful interference. Emissions from spaceborne or airborne stations can be particularly serious sources of interference to the radio astronomy service (see Nos. 343/S4.5 and 344/S4.6 and Article 36/S29).

S5.333 In the bands 1215–1300 MHz, 3100–3300 MHz, 5250–5350 MHz, 8550–8650 MHz, 9500–9800 MHz and 13.4–14.0 GHz, radiolocation stations installed on spacecraft may also be employed for the earth exploration-satellite and space research services on a secondary basis.

S5.441 The use of the bands 4500–4800 MHz (space-to-Earth), 6725–7025 MHz (Earth-to-space), 10.7–10.95 GHz (space-to-Earth), 11.2–11.45 GHz (space-to-Earth) and 12.75–13.25 GHz (Earth-to-space) by the fixed-satellite service shall be in accordance with the provisions of Appendix 30B/S30B.

S5.484 In Region 1, the use of the band 10.7–11.7 GHz by the fixed-satellite service (Earth-to-space) is limited to feeder links for the broadcasting-satellite service.

S5.497 The use of the band 13.25–13.4 GHz by the aeronautical radionavigation service is limited to Doppler navigation aids.

S5.498 The band 13.25–13.4 GHz may also be used in the space research service (Earth-to-space) on a secondary basis, subject to agreement obtained under Article 14/No. S9.21.

S5.499 *Additional allocation:* in Bangladesh, India and Pakistan, the band 13.25–14 GHz is also allocated to the fixed service on a primary basis.

S5.500 *Additional allocation:* in Algeria, Angola, Saudi Arabia, Bahrain, Brunei Darussalam, Cameroon, the Republic of Korea, Egypt, the United Arab Emirates, Gabon, Guinea, Indonesia, the Islamic Republic of Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Madagascar, Malaysia, Malawi, Mali, Malta, Morocco, Mauritania, Niger, Nigeria, Pakistan, Qatar, Syria, Senegal, Singapore, Sudan, Chad and Tunisia, the band 13.4–14 GHz is also allocated to the fixed and mobile services on a primary basis.

S5.501 *Additional allocation:* in Armenia, Austria, Azerbaijan, Belarus, Bulgaria, Georgia, Hungary, Japan, Kazakhstan, Moldova, Mongolia, Kyrgyzstan, Romania, the United Kingdom, Russia, Tajikistan, Turkmenistan and Ukraine, the band 13.4–14 GHz is also allocated to the radionavigation service on a primary basis.

S5.502 In the band 13.75–14 GHz, the e.i.r.p. of any emission from an earth station in the fixed-satellite service shall be at least 68 dBW, and should not exceed 85 dBW, with a minimum antenna diameter of 4.5 metres. In addition the e.i.r.p., averaged over one second, radiated by a station in the radiolocation or radionavigation services towards the geostationary-satellite orbit shall not exceed 59 dBW.

S5.503 In the band 13.75–14 GHz, geostationary space stations in the space research service for which information for advance publication has been received by the Bureau prior to 31 January 1992 shall operate on an equal basis with stations in the fixed-satellite service; after that date, new geostationary space stations in the space research service will operate on a secondary basis. The e.i.r.p. density of emissions from any earth station in the fixed-satellite service shall not exceed 71 dBW per 6 MHz in the frequency range 13.772–13.778 GHz until those geostationary space stations in the space research service for which information for advance publication has been received by the Bureau prior to 31 January 1992 cease to operate in this band. Automatic power control may be used to increase the e.i.r.p. density above 71 dBW per 6 MHz in this frequency range to compensate for rain attenuation, to the extent that the power-flux density at the fixed-satellite service space station does not exceed the value resulting from use of 71 dBW per 6 MHz e.i.r.p. in clear sky conditions.

S5.503A Until 1 January 2000, stations in the fixed-satellite service shall not cause harmful interference to non-geostationary space stations in the space research and Earth exploration-satellite services. After that date, these non-geostationary space stations will operate on a secondary basis in relation to the fixed-satellite service. Additionally, when planning earth stations in the fixed-satellite service to be brought into service between 1 January 2000 and 1 January 2001, in order to accommodate the needs of spaceborne precipitation radars operating in the band 13.793–13.805 GHz, advantage should be taken of the consultation process and the information given in Recommendation ITU–R SA.1071.

S5.504 The use of the band 14–14.3 GHz by the radionavigation service shall be such as to provide sufficient protection to space stations of the fixed-satellite service (see Recommendation 708).

S5.505 *Additional allocation:* in Algeria, Angola, Saudi Arabia, Australia, Bahrain, Bangladesh, Botswana, Brunei Darussalam, Cameroon, China, the Congo, the Republic of Korea, Egypt, the United Arab Emirates, Gabon, Guatemala, Guinea, India, Indonesia, the Islamic Republic of Iran, Iraq, Israel, Japan, Jordan, Kuwait, Lesotho, Lebanon, Malaysia, Malawi, Mali, Morocco, Mauritania, Niger, Oman, Pakistan, the Philippines, Qatar, Syria, the Democratic People's Republic of Korea, Senegal, Singapore, Somalia, Sudan, Swaziland, Tanzania, Chad and Yemen, the band 14–14.3 GHz is also allocated to the fixed service on a primary basis.

S5.506 The band 14–14.5 GHz may be used, within the fixed-satellite service (Earth-to-space), for feeder links for the broadcasting-satellite service, subject to coordination with other networks in the fixed-satellite service. Such use of feeder links is reserved for countries outside Europe.

S5.508 *Additional allocation:* in Germany, Austria, Belgium, Bosnia and Herzegovina, Denmark, Spain, France, Greece, Ireland, Iceland, Italy, The Former Yugoslav Republic of Macedonia, Libya, Liechtenstein, Luxembourg, Norway, Portugal, the United Kingdom, Slovenia, Switzerland, Turkey and Yugoslavia, the band 14.25–14.3 GHz is also allocated to the fixed service on a primary basis.

S5.509 *Additional allocation:* in Japan and Pakistan the band 14.25–14.3 GHz is also allocated to the mobile, except aeronautical mobile, service on a primary basis.

II. Old Numbering Scheme

* * * * *

United States (US) Footnotes

* * * * *

US110 In the frequency bands 3100–3300 MHz, 3500–3700 MHz, 5250–5350 MHz, 8500–9000 MHz, 9200–9300 MHz, 9500–10000 MHz, 13.4–14.0 GHz, 15.7–17.3 GHz, 24.05–24.25 GHz and 33.4–36.0 GHz, the non-Government radiolocation service shall be secondary to the Government radiolocation service and to airborne doppler radars at 8800 MHz, and shall provide protection to airport surface detection equipment (ASDE) operating between 15.7–16.2 GHz.

* * * * *

US337 In the band 13.75–13.80 GHz, earth stations in the fixed-satellite service shall be coordinated on a case-by-case basis through the frequency assignment

subcommittee in order to minimize harmful interference to the Tracking and Data Relay Satellite System's forward space-to-space link (TDRSS forward link-to-LEO).

* * * * *

PART 25—SATELLITE COMMUNICATIONS

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

Authority: Secs. 25.101 to 25.601 issued under Sec. 4, 48 Stat. 1066, as amended; 47 U.S.C. 154. Interpret or apply secs. 101–104, 76 Stat. 419–427; 47 U.S.C. 701–744; 47 U.S.C. 554.

2. Section 25.202(a)(1) is revised to read as follows:

§ 25.202 Frequencies, frequency tolerance and emission limitations.

(a)(1) *Frequency bands.* The following frequencies are available for use by the fixed-satellite service. Precise frequencies and bandwidths of emission shall be assigned on a case-by-case basis.

Space-to-Earth (GHz)	Earth-to-space (GHz)
3.7–4.2 [1]	[1] 5.925–6.425
10.95–11.2 [1]	[4] 13.75–14.0
11.45–11.7 [2]	[5] 14.0–14.2
11.7–12.2 [3]	14.2–14.5
17.7–19.7 [1]	[1] 27.5–29.5
19.7–20.2	29.5–30.0

[1] This band is shared coequally with terrestrial radiocommunication services.

[2] Use of this band by the fixed-satellite service is limited to international systems, i.e., other than domestic systems.

[3] Use of this band by the fixed-satellite service in Region 2 is limited to national and subregional systems. Fixed-satellite transponders may be used additionally for transmissions in the broadcasting-satellite service.

[4] This band is shared on an equal basis with the Government radiolocation service, grandfathered space stations in the Tracking and Data Relay Satellite System, and until January 1, 2000, spaceborne sensors.

[5] In this band, stations in the radionavigation service shall operate on a secondary basis to the fixed-satellite service.

* * * * *

3. Section 25.204(f) is added to read as follows:

§ 25.204 Power limits.

* * * * *

(f) The e.i.r.p. of any emission from an earth station operating in the frequency band 13.75–14.0 GHz shall be at least 68 dBW and shall not exceed 85 dBW, with a minimum antenna diameter of 4.5 meters; except in the frequency band 13.772–13.778 GHz, where the e.i.r.p. shall be at least 68 dBW and shall not exceed 71 dBW per 6 MHz, with a minimum antenna diameter of 4.5 meters. Automatic power control may be used to increase the e.i.r.p. density above 71 dBW per 6 MHz to compensate for rain attenuation to the extent that the power flux density at the fixed-satellite space station does not exceed the value resulting from use of 71 dBW per 6 MHz e.i.r.p. in clear sky conditions.

PART 90—PRIVATE LAND MOBILE RADIO SERVICES

1. The authority citation for Part 90 continues to read as follows:

Authority: Sections 4, 303, 309 and 332, 48 Stat. 1066, 1082, as amended; 47 U.S.C. §§ 154, 303, 309 and 332, unless otherwise amended.

2. Section 90.103(b) is amended in the table by removing the entry for the 13,400–14,000 MHz band, and adding entries for 13,400 to 13,750 MHz band and 13,750 to 14,000, by revising paragraph (c)(12), and by adding paragraph (c)(31) to read as follows:

§ 90.103 Radiolocation Service.

* * * * *

(b) * * *

RADIOLOCATION SERVICE FREQUENCY TABLE

Frequency or band	Class of station(s)	Limitation
* * * * *		
Megahertz:		
* * * * *		
13,400 to 13,750.	.....do	12
13,750 to 14,000.	.....do	31
* * * * *		

* * * * *

(c) * * *

(12) This frequency is shared with and is on a secondary basis to the Government Radiolocation Service.

* * * * *

(31) This frequency band is shared with and is on secondary basis to the Fixed-Satellite Service and to the Government's Radiolocation, Space Research and Earth Exploration-Satellite Services. After January 1, 2000, the Government's Space Research and Earth Exploration-Satellite Services shall operate on a co-equal secondary basis with the non-Government Radiolocation Service, except that grandfathered space stations in the Tracking and Data Relay Satellite System shall continue to be protected from harmful interference.

* * * * *

[FR Doc. 96–25236 Filed 10–4–96; 8:45 am]

BILLING CODE 6712–01–P

47 CFR Parts 64 and 68

[CC Docket 96–128; FCC 96–388]

Pay Telephone Reclassification and Compensation Provisions of the Telecommunications Act of 1996

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Federal Communications Commission (''Commission'') adopts a *Report and Order* implementing Section 276 of the Communications Act of 1934, as amended by the Telecommunications Act of 1996 (''1996 Act''). In the *Report and Order,* the Commission adopts new rules and policies governing the payphone industry that: establish a plan to ensure fair compensation for ''each and every completed intrastate and interstate call using [a] payphone[,]'' discontinue intrastate and interstate carrier access charge payphone service elements and payments and intrastate and interstate payphone subsidies from basic exchange services, prescribe nonstructural safeguards for Bell Operating Company (''BOC'') payphones, permit the BOCs to negotiate with payphone location providers on the interLATA carrier presubscribed to their payphones, permit all payphone service providers to negotiate with location providers on the intraLATA carrier presubscribed to their payphones, and adopt guidelines for use by the states in establishing public interest payphones to be located ''where there would otherwise not be a payphone[.]'' As set forth in the *Report and Order* and explained below, the Commission is issuing the *Report and Order* to comply with the statutory mandate of Section 276 of the 1996 Act of ''promot[ing] competition among payphone service providers and promot[ing] the widespread deployment of payphone services to the benefit of the general public * * *.''

EFFECTIVE DATES: The revision of the heading of subpart M and the authority citation of part 64 and the amendment to § 64.1301 and new § 64.1340 become effective November 6, 1996. The amendments to § 64.703 and new § 64.1330 become effective December 16, 1996. Section 64.1301 is removed and §§ 64.1300, 64.1310 and 64.1320 become effective October 7, 1997. Sections 68.2 and 68.3 become effective April 15, 1997.

FOR FURTHER INFORMATION CONTACT: Michael Carowitz, 202–418–0960, Enforcement Division, Common Carrier Bureau.

SUPPLEMENTARY INFORMATION: On June 4, 1996, the Commission adopted a Notice of Proposed Rulemaking (''NPRM'') [61 FR 33074] to implement Section 276 of the Telecommunications Act of 1996. This is a summary of the Commission's *Report and Order* in CC Docket No. 96–128, adopted and released on September 20, 1996. The full text of the *Report and Order* is available for inspection and copying during normal business hours in the FCC Reference Center, Room 239, 1919 M Street, N.W., Washington, D.C. The complete text of the *Report and Order* may also be purchased from the Commission's duplicating contractor, International Transcription Services, 2100 M Street, N.W., Suite 140, Washington, D.C. 20037, (202) 857–3800. The *Report and Order* contains new or modified information collections 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 new or modified information collections contained in this proceeding.

Parties must file any petitions for reconsideration of the *Report and Order* within 30 days from release of that document. The Commission waives the requirements of Section 1.4 of its rules to establish this new date of public notice in light of the deadline established in the 1996 Act to complete this proceeding. Parties may file oppositions to the petitions for reconsideration pursuant to Section 1.106(g) of the rules, except that oppositions to the petitions must be filed within seven (7) days after the date for filing the petitions for reconsideration. The Commission will not issue a separate notice of any petitions for reconsideration; the *Report and Order* serves as notice to all interested parties of the due dates for petitions and oppositions. In addition, the Commission waives Section 1.106(h) of the rules and will not accept reply comments in response to oppositions. The Commission concludes that these actions are necessary to complete all Commission action in this proceeding, which involves issues concerning the expedited implementation of the 1996 Act, by the statutory deadline of November 8, 1996. The Commission will consider all relevant and timely petitions and oppositions before final action is taken in this proceeding.

Petitions for reconsideration must comply with Sections 1.106 and 1.49 and all other applicable sections of the Commission's rules. Petitions also must clearly identify the specific portion of the *Report and Order* for which relief is sought. If a portion of a party's arguments does not fall under a particular topic listed in the outline of the *Report and Order*, such arguments should be included in a clearly labeled section at the beginning or end of the filing. Parties may not file more than a total of ten (10) pages of *ex parte* submissions, excluding cover letters. This 10 page limit does not include: (1) written *ex parte* filings made solely to disclose an oral *ex parte* contact; (2) written material submitted at the time of an oral presentation to Commission staff that provides a brief outline of the presentation; or (3) written material filed in response to direct requests from Commission staff. *Ex parte* filings in excess of this limit will not be considered as part of the record in this proceeding.

To file a petition for reconsideration in this proceeding parties must file an original and ten copies of all petitions and oppositions. Petitions and oppositions should be sent to the Office of the Secretary, Federal Communications Commission, Washington, DC 20554. If parties want each Commissioner to have a personal copy of their documents, an original plus fourteen copies must be filed. In addition, participants should submit two additional copies directly to the Common Carrier Bureau, Enforcement Division, Room 6008, 2025 M Street NW, Washington, D.C. 20554. The petitions and oppositions will be available for public inspection during regular business hours in the Dockets Reference Room (Room 230) of the Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554. Copies of the petition and any subsequently filed documents in this matter may be obtained from ITS, Inc., 2100 M Street, NW., Suite 140, Washington, DC 20037, (202) 857–3800.

Paperwork Reduction Act

The Report and Order contains a new or modified information collection. 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 following information collections contained in the *Report and Order* as required by the Paperwork Reduction Act of 1995, Public Law No. 104–13. OMB notification of action is due 60 days from the date of publication of the *Report and Order* in the Federal Register. Comments should address: (a) whether the proposed or modified information collection 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: None.

Title: Implementation of the Payphone Reclassification and Compensation Provisions of the Telecommunications Act of 1996, CC Docket No. 96–128.

Form No.: N/A.

Type of Review: New collections.

Respondents: State, local or tribal government; business or other for-profit, including small businesses.

Section/title	Number of respondents	Estimated time per response (hours)	Total Annual burden (hours)
a. State Review/Removal of State Regulations Concerning Adequacy of Local Coin Rate Disclosure	50	50	2,500
b. State Review/Removal of Market Entry or Exit Requirements	50	50	2,500
c. State Showing of Proof of Market Failure for Exception to Market-Rate Local Coin Call Requirement	50	50	2,500
d. State Review/Removal of Adequacy of Provision of Public Interest Payphones	50	50	2,500
e. Payphone Providers' Transmission of Specific Payphone Coding Digits	[1] 197	20	3,940
f. Interexchange Carriers' Provision of Tracking of All Compensable Calls	275	100	27,500
g. Interexchange Carriers' Initiation of Annual Verification of Per Call Tracking Functions	275	20	5,500
h. LEC Verification of Disputed ANIs and Maintaining and Making Available the Verification Data	400	.5	800
i. LEC Provision of Timely Notification of Payphone Disconnection	400	.5	200
j. LEC Indication on the Payphone's Monthly Bill That the Amount Due is for Payphone Services	400	10	4,000

Section/title	Number of respondents	Estimated time per response (hours)	Total Annual burden (hours)
k. LEC Tariff Filings	400	100	40,000
l. Reclassification of LEC–Owned Payphones	400	100	40,000
m. Reclassification of AT&T Payphones	1	100	100
n. Payphone Provider's Verification of its Status to IXC Paying Compensation	[1] 197	1	197
o. Payphone Provider's Posting of Local Coin Call Rate on Each Payphone Placard	197	20	3,940

[1] This estimate was obtained by reference to the Regulatory Flexibility Analysis in the *Implementation of the Local Competition Provisions of the Telecommunications Act of 1996,* Report and Order, CC Docket No. 96–98, FCC 96–325 (rel. August 8, 1996).[2] *Id.*

Total Annual Burden: 136,177 hours.

Estimated Costs per Respondent: $0.

Needs and Uses: The new and modified collections in this Report and Order are necessary to implement the provisions of Section 276 of the Telecommunications Act of 1996.

OMB Approval Number: 3060–0721.

Title: Report of Local Exchange Companies (''LECs'') of Cost Accounting Studies.

Form No.: N/A.

Type of Review: Revised Collection.

Respondents: Business or other for-profit, including small businesses.

Number of Respondents: 400.

Estimated Time per Response: 50 hours.

Total Annual Burden: 20,000 hours.

Estimated Cost per Respondent: $0.

Needs and Uses: Pursuant to the mandate in Section 276(b)(1)(A) to ''establish a per call compensation plan to ensure that all payphone service providers are fairly compensated for each and every completed intrastate and interstate call'', 47 U.S.C. § 276(b)(1)(A), incumbent LECs are required to offer individual central office coin transmission services to payphone service providers (''PSPs'') under a nondiscriminatory, public tariffed offering if the LECs provide those services for their own operations. Because the incumbent LECs may have an incentive to charge their competitors unreasonably high prices for these services, the Commission requires them to submit cost support for their central office coin services, on a one-time basis. The report would contain engineering studies, time and wage studies, and other cost accounting studies to identify the direct cost of central office coin services. This will ensure that the services are reasonably priced and do not include subsidies.

OMB Approval Number: 3060–0719.

Title: Quarterly Report of IntraLATA Carriers Listing Payphone Automatic Number Identification (ANIs).

Form No.: N/A.

Type of Review: Revised collection.

Respondents: Business or other for-profit, including small businesses.

Number of Respondents: 400.

Estimated Time per Response: 3.5 hours.

Total Annual Burden: 5,600 hours.

Estimated Cost per Respondent: $0.

Needs and Uses: Pursuant to the mandate in Section 276(b)(1)(A) to ''establish a per call compensation plan to ensure that all payphone service providers are fairly compensated for each and every completed intrastate and interstate call'', 47 U.S.C. § 276(b)(1)(A), intraLATA carriers are required to provide to interexchange carriers (''IXCs'') a quarterly report listing payphone automatic payphone identifications (''ANIs''). Without provision of this report, resolution of disputed ANIs would be rendered very difficult. IXCs would not be able to discern which ANIs pertain to payphones and therefore would not be able to ascertain which dial-around calls were originated by payphones for compensation purposes. There would be no way to guard against possible fraud. Without this collection, lengthy investigations would be necessary to verify claims. The report allows IXCs to determine which dial-around calls are made from payphones. The data, which must be maintained for at least 18 months after the close of a compensation period, will facilitate verification of disputed ANIs. The Order does not specify the manner in which IntraLATA carriers must provide carrier-payors with the list of payphone ANIs. IntraLATA carriers are free to use any technologies at their disposal to distribute the necessary information, including innovative approaches such as posting the information on the Internet or distributing the information via electronic mail.

OMB Approval Number: 3060–0723.

Title: Public Disclosure of Network Information by Bell Operating Companies (''BOCs'').

Form No.: N/A.

Type of Review: Revised collections.

Respondents: Business or other for-profit, including small businesses.

Number of Respondents: 7.

Estimated Time per Response: 50 hours.

Total Annual Burden: 350 hours.

Estimated Cost per Respondent: $0.

Needs and Uses: Pursuant to Section 276(b)(1)(C) provisions that prescribe a set of nonstructural safeguards for BOC payphone services, to foster development of competition in the provision of local telephone service, 47 U.S.C. § 276(B)(1)(C), the BOCs are required to publicly disclose changes in their networks or new network services at two different points in time. First, disclosure would occur at the ''make/buy'' point: when a BOC decides to make for itself, or procure from an unaffiliated entity, any product whose design affects or relies on the network interface. Second, a BOC would publicly disclose technical information about a new service 12 months before it is introduced. If the BOC could introduce the service within 12 months of the make/buy point, it would make a public disclosure at the make/buy point. In no event, however, would the public disclosure occur less than six months before the introduction of the service. Without provision of these reports, the industry would be unable to ascertain whether the BOCs designing new network services or changing network technical specifications are to the advantage of their own payphones, or might disadvantage BOC payphone competitors. The requirement for a minimum 6-month period of public disclosure prior to the introduction of a new service is vital to ensure that BOCs do not design new network services or change network technical specifications to the advantage of their own payphones.

OMB Approval Number: 3060–0724.

Title: Annual Report of IXCs Listing the Compensation Amount Paid to Payphone Providers and the Number of Payees.

Form No.: N/A.

Type of Review: Revised collection.

Respondents: Business or other for-profit, including small businesses.

Number of Respondents: 275.

Estimated Time per Response: 2 hours.

Total Annual Burden: 550 hours.

Estimated Cost per Respondent: $0.

Needs and Uses: Pursuant to the mandate in Section 276(b)(1)(A) to ''establish a per call compensation plan to ensure that all payphone service providers are fairly compensated for each and every completed intrastate and interstate call'', 47 U.S.C. § 276(b)(1)(A), IXCs, who are responsible for paying per-call compensation to payphone providers, are required to provide annual reports to the Common Carrier Bureau listing the amount of compensation paid to payphone providers and the number of payees. Without provision of this report, the Commission would be unable to ensure that all the IXCs are paying their respective compensation obligations. The report is intended to be very brief, and the reporting requirement will be terminated after the carriers have filed their reports for the 1999 calendar year. In addition, for further flexibility, the Chief, Common Carrier Bureau, is delegated the authority to establish the details, as necessary, of this annual report, including the authority to extend or limit the scope of this report.

OMB Approval Number: 3060–0726.

Title: Quarterly Report of IXCs Listing the Number of Dial Around Calls for Which Compensation is Being Paid to Payphone Owners.

Form No.: N/A.

Type of Review: Revised collections.

Respondents: Business or other for-profit, including small businesses.

Number of Respondents: 275.

Estimated Time per Response: 2 hours.

Total Annual Burden: 550 hours.

Estimated Cost per Respondent: $0.

Needs and Uses: Pursuant to the mandate in Section 276(b)(1)(A) to ''establish a per call compensation plan to ensure that all payphone service providers are fairly compensated for each and every completed intrastate and interstate call'', 47 U.S.C. § 276(b)(1)(A), IXCs, who are responsible for paying per-call compensation to payphone providers are required to provide to payphone providers a quarterly report listing the dial-around calls made from each payphone provider's payphones. Without provision of this report, payphone providers would be unable to ascertain the compensation amount to be paid by the IXCs. The report allows each payphone provider to determine how many dial-around calls to the IXC generating the report were originated by each of the payphone provider's payphones. The Commission weighed several alternatives to achieve optimum efficiency and the least burdensome approach, before imposing this requirement. This requirement is imposed on the IXCs because they have the greatest ability and incentive to establish the most efficient means of administering the payment of compensation.

SUMMARY OF REPORT AND ORDER

I. Background

1. Section 276(b)(1)(A) of the 1996 Act directs the Commission to establish a compensation plan to ensure ''that all payphone service providers are fairly compensated for each and every completed intrastate and interstate call'' from their payphones. Section 276(b)(1)(B) mandates that the Commission ''discontinue the intrastate and interstate carrier access charge payphone service elements and payments * * * and all intrastate and interstate subsidies from basic exchange and exchange access revenues.'' In addition, Section 276(b)(1)(D) directs the Commission to consider whether BOCs should be granted certain rights already available to all other payphone service providers (''PSPs'') to participate in the location provider's selection of presubscribed interLATA carrier, while Section 276(b)(1)(E) grants certain rights to all PSPs to participate in the selection of presubscribed intraLATA carriers. Together with the other subsections of Section 276, these three provisions help to establish regulatory parity for all PSPs, whether independent payphone providers or incumbent LECs (both independent LECs and BOCs).

II. Discussion

2. In the *Report and Order,* the Commission adopts new rules and policies governing the payphone industry that: (1) establish a plan to ensure fair compensation for ''each and every completed intrastate and interstate call using [a] payphone[;]'' (2) discontinue intrastate and interstate carrier access charge payphone service elements and payments and intrastate and interstate payphone subsidies from basic exchange services; (3) prescribe nonstructural safeguards for Bell Operating Company (''BOC'') payphones; (4) permit the BOCs to negotiate with payphone location providers on the interLATA carrier presubscribed to their payphones; (5) permit all payphone service providers to negotiate with location providers on the intraLATA carrier presubscribed to their payphones; and (6) adopt guidelines for use by the states in establishing public interest payphones to be located ''where there would otherwise not be a payphone[.]''

3. The Telecommunications Act of 1996 fundamentally changes telecommunications regulation. The 1996 Act erects a ''pro-competitive deregulatory national framework designed to accelerate rapid private sector deployment of advanced telecommunications and information technologies and services to all Americans by opening all telecommunications markets to competition.'' In this proceeding the Commission advances the twin goals of Section 276 of the Act of ''promot[ing] competition among payphone service providers and promot[ing] the widespread deployment of payphone services to the benefit of the general public * * *.'' To this end, the Commission seeks to eliminate those regulatory constraints that inhibit the ability both to enter and exit the payphone marketplace, and to compete for the right to provide services to customers through payphones. At the same time, the Commission recognizes that a transition period is necessary to eliminate the effects of some long-standing barriers to full competition in the payphone market. For this reason, the Commission will continue for a limited time to regulate certain aspects of the payphone market, but only until such time as the market evolves to erase these sources of market distortions.

A. Compensation for Each and Every Completed Intrastate and Interstate Call Originated by Payphones

4. In the *Report and Order,* consistent with Section 276, the Commission establishes a plan to ensure fair compensation for all calls. The Commission concludes that fair compensation can be ensured best when the PSP can track the calls made from the payphone on a call-by-call basis and be assured efficient payment for those calls; when the market can set a fair rate for the call; and when the caller has the information necessary to make an informed choice as to whether to make the call and incur the compensation charge.

1. Payphone Calls Subject to this Rulemaking and Compensation Amount

5. The Commission concludes that, once competitive market conditions exist, the most appropriate way to ensure that PSPs receive fair compensation for each call is to let the market set the price for individual calls originated on payphones. It is only in cases where the market does not or cannot function properly that the Commission needs to take affirmative steps to ensure fair compensation, such as in the following situations. First, because the Telephone Operator Consumer Services Improvement Act (TOCSIA) requires all payphones to

unblock access to alternative operator service providers (OSPs) through the use of access codes (including 800 access numbers), PSPs cannot block access to toll free numbers generally. However, TOCSIA does not prohibit an interexchange carrier (IXC) from blocking subscriber 800 numbers from payphones, particularly if the IXC wants to avoid paying the per-call compensation charge on these calls. This uneven bargaining between parties necessitates the Commission's involvement. Second, the Commission concludes that each state should, in light of the instant proceeding, examine and modify its regulations applicable to payphones and PSPs, particularly those rules that impose market entry or exit requirements, and others that are not competitively neutral and consistent with the requirements of Section 276 of the Act. The Commission concludes that, for purposes of ensuring fair compensation through a competitive marketplace, states need only remove those regulations that restrict competition, and they need not address those regulations that, on a competitively neutral basis, provide consumers with information and price disclosure. Third, the Commission concludes that callers should have information in every instance about the price of the calls they make from payphones. To this end, the Commission requires that each payphone clearly indicate the local coin rate within the informational placard on each payphone.

6. While the most appropriate way to ensure fair compensation is to let the market set the price for individual payphone calls, the Commission concludes that this transition to market-based rates should occur in two phases. Because local exchange carriers (LECs) will terminate, pursuant to Section 276(b)(1)(b), subsidies for their payphones within one year of the effective date of the rules adopted in this proceeding, LECs will not be eligible to receive compensation under Section 276(b)(1)(a) until that termination date. This one-year period before per-call compensation is effective, as discussed below, will be the first phase of implementing the rules adopted in this proceeding. During this first phase, states may continue to set the local coin rate in the same manner as they currently do. States may, however, move to market-based local coin rates anytime during this one-year period. In addition, the states must conduct its examination of payphone regulations during this one-year period to review and remove, if necessary, those regulations that affect competition, such as entry and exit restrictions. IXCs will pay compensation for access code calls and subscriber 800 calls on a flat-rate basis. In addition, all payphones must provide free access to dialtone, emergency calls, and telecommunications relay service calls for the hearing disabled.

7. In the second phase, which will begin one year after the effective date of rules adopted in this proceeding, LECs will have already terminated the subsidies prohibited by Section 276(b)(1)(B), and per-call tracking capabilities will be in place. The carriers to whom payphone calls are routed will be responsible for tracking each compensable call and remitting per-call compensation to the PSP. During this second year, which is the first year of per-call compensation (as opposed to flat-rate compensation), the market will be allowed to set the rate for local coin calls, unless the state can show that there are market failures within the state that would not allow market-based rates. In addition, during the second phase, which will be the first year of per-call compensation (after the initial year of flat-rate compensation), to allow the Commission to ascertain the status of competition in the payphone marketplace, the Commission concludes that IXCs must pay PSPs a default rate of $.35 for each compensable call, which may be changed by mutual agreement. PSPs will be required to post the local coin rate they choose to charge at each payphone. During the second phase, the Commission may review, at the Commission's option, the deregulation of local coin rates nationwide and determine whether marketplace disfunctions exist, such as locational monopolies caused by the size of the location with an exclusive PSP contract or the caller's lack of time to identify potential substitute payphones, and should be addressed by the Commission. If the Commission finds that the deregulation of local coin rates warrants a modification of its approach due to market failures, the Commission may choose to set a cap on the number of calls subject to compensation from particular payphones to limit the exercise of locational market power. Absent such a finding, at the conclusion of the second phase, the market-based local coin rate at these payphones will be the default compensation rate for all compensable calls in absence of an agreement between the PSP and the carrier-payor.

8. *Ensuring Fair Compensation.* To ensure fair compensation, the Commission concludes that it must provide for compensation for access code calls and subscriber 800 and other toll-free number calls, whether they are intrastate or interstate in destination.

9. The Commission concludes that it must ensure fair compensation for 0+ calls that use BOC payphones. The Commission concludes that once the BOCs reclassify their payphones and terminate all subsidies, pursuant to Section 276(b)(1)(B), they may receive the per-call compensation established by the *Report and Order,* so long as they do not otherwise receive compensation for use of their payphones in originating 0+ calls. The Commission concludes further that, in the absence of a contract providing compensation to the PSP for intraLATA 0+ calls, the PSP shall be eligible to collect per-call compensation from the carrier to whom the call is routed. The Commission also concludes that when a caller dials ''0'' and the payphone subsequently translates this digit, unbeknownst to the caller, into an 800 access number (*i.e.,* as a way of presubscribing the payphone to a particular IXC), such a call is not compensable as an access code call, because it does not put the caller into contact with an alternative carrier.

10. The Commission concludes that PSPs should receive compensation for international calls. The Commission concludes that it has authority under Sections 4(i) and 201(b) of the Communications Act of 1934, as amended, to ensure that PSPs are fairly compensated for international as well as interstate and intrastate calls using their payphones in the United States.

11. *Local Coin Calls.* The Commission concludes that full and unfettered competition is the best way of achieving Congress' dual objectives to promote ''competition among payphone service providers and promote the widespread deployment of payphone services to the benefit of the general public.'' Once competitive conditions exist, the Commission believes that the market should set the compensation amount for all payphone calls, including local coin calls. Because the Commission has an obligation under Section 276 to ensure that the compensation for all local coin calls is fair, it concludes that the market should be allowed to set the price for all compensable calls, including a local coin call.

12. Section 276(b)(1)(A) gives the Commission both the jurisdiction to ensure fair compensation for local coin calls and the mandate to establish a plan to compensate PSPs on a per-call basis. Based on the record in this proceeding, the Commission concludes that a deregulatory, market-based approach to setting local coin rates is appropriate, because existing local coin rates are not

necessarily fairly compensatory. The Commission recognizes, however, that the competitive conditions, which are a prerequisite to a deregulatory, market-based approach, do not currently exist and cannot be achieved immediately. Many states impose regulations on PSPs, including certain requirements that must be fulfilled before a PSP can enter or exit the payphone marketplace. In addition, in some locations, because of the size of the location with an exclusive PSP contract or the caller's lack of time to identify potential substitute payphones, the PSP may be able to charge an inflated rate for local calls based on its monopoly, pursuant to an exclusive contract with the location provider, on all payphones at the location. The Commission concludes that such monopoly arrangements, in the absence of regulatory oversight, could impair competition.

13. Based on these concerns, the Commission concludes that the overall transition to market-based local coin rates should not occur immediately. As discussed below, LECs will not be required to terminate, pursuant to Section 276(b)(1)(b), certain subsidies associated with their payphones until April 15, 1997. LECs will not be eligible to receive per-call compensation under Section 276(b)(1)(a) for one year, when all such subsidies are terminated. For this one-year period, the states will be responsible for both ensuring that PSPs are fairly compensated for local coin calls and protecting consumers from excessive rates. Eventually, when fully competitive conditions exist, the marketplace will address both concerns. The Commission concludes that, during this one-year period before per-call, as opposed to flat-rate, compensation becomes effective, states may continue to set the local coin rate in the same manner as they currently do. States may, however, move to market-based local coin rates anytime during this one-year period, and are encouraged to do so. In addition, the Commission concludes that during the same period, the states should take additional action to ensure that payphone competition is promoted. The Commission believes that ease of entry and exit in this market will foster competition and allow the market, rather than regulation, to dictate the behavior of the various parties in the payphone industry. To this end, each state should examine and modify its regulations applicable to payphones and PSPs, removing, in particular, those rules that impose market entry or exit requirements. The Commission concludes that, for purposes of ensuring fair compensation through a competitive marketplace, the states should remove only those regulations that affect payphone competition; the states remain free at all times to impose regulations, on a competitively neutral basis, to provide consumers with information and price disclosure. In addition, the states at all times must ensure that access to dialtone, emergency calls, and telecommunications relay service calls for the hearing disabled is available from all payphones at no charge to the caller.

14. At the conclusion of this first one-year period, the market will be allowed to set the price for a local coin call, as discussed more fully above. However, the Commission concludes that it should make an exception to the market-based approach for states that are able to demonstrate to the Commission that there are market failures within the state that would not allow market-based rates. Such a detailed showing could consist of, for example, a detailed summary of the record of a state proceeding that examines the costs of providing payphone service within that state and the reasons why the public interest is served by having the state set rates within that market. In addition, under the Commission's deregulatory, market-based approach, when states have concerns about possible market failures, such as that of payphone locations that charge monopoly rates, they are empowered to act by, for example, mandating that additional PSPs be allowed to provide payphones, or requiring that the PSP secure its contract through a competitive bidding process that ensures the lowest possible rate for callers. If a market failure persists after such action, the state should recommend the matter to the Commission for possible investigation. In addition, during the second phase, after the initial year of flat-rate compensation, the Commission may review, at its option, the deregulation of local coin rates nationwide and determine whether marketplace disfunctions, such as locational monopolies where the size of the location or the caller's lack of time to identify potential substitute payphones, exist and should be addressed by the Commission. At this point, if the Commission finds that the deregulation of local coin rates warrants a modification of its approach due to market failures, the Commission may choose, for example, to set a cap on the number of calls subject to compensation from particular payphones to limit the exercise of locational market power. Absent such a finding, at the conclusion of the second phase, the market-based local coin rate at these payphones will be the default compensation rate for all compensable calls in absence of an agreement between the PSP and the carrier-payor.

15. With regard to ''411'' directory-assistance calls, the Commission noted that, while incumbent LECs in many jurisdictions currently do not charge the payphone caller for ''411'' calls made from their own phones, the LECs charge independent payphone providers for directory-assistance calls made from their payphones, and are not always allowed by the state to pass those charges on to callers. The Commission concludes that it must ensure fair compensation for ''411'' and other directory assistance calls from payphones by permitting the PSP to charge a market-based rate for this service, although a PSP may decline to charge for this service if it chooses. In addition, to help ensure that a LEC does not discriminate in favor of its own payphones, the Commission concludes that if the incumbent LEC imposes a fee on independent payphone providers for ''411'' calls, then the LEC must impute the same fee to its own payphones for this service.

16. *Completed Calls.* The Commission concludes that a ''completed call'' is a call that is answered by the called party. The Commission has previously found that, where an 800 calling card call is routed through an IXC's platform, it should not be viewed as two distinct calls—one to the platform and one to the called party. In addition, in *Florida Public Telecommunications Ass'n* v. *FCC*, the United States Court of Appeals for the District of Columbia Circuit emphasized the one-call nature of a subscriber 800 call from the caller's point of view. To comply with this the mandate of Section 276, the Commission concludes that multiple sequential calls made through the use of a payphone's ''#'' button should be counted as separate calls for compensation purposes.

17. The Commission concludes that Section 276(b)(1)(A) was not intended to apply to both incoming and outgoing calls. Because PSPs may block incoming calls, they are able to restrict use of their payphones if they are concerned about a lack of compensation. For this reason, the Commission concludes that incoming calls are not within the purview of Section 276, and it is not required, as a result, to address them in the order.

18. *Payphone Fraud.* The Commission has recognized, since it first addressed the issue of compensation for subscriber

800 calls in 1991, that a PSP ''could attach an autodialer to a payphone and have it place repeated 800 calls * * * to increase the amount of compensation [it] receives.'' Section 227(b)(1) of the Act states that it is unlawful for any person to use an autodialer to call ''any service for which the called party is charged for the call[.]'' The Commission concludes that this provision bars the use of autodialers to generate payphone compensation by calling toll-free 800 numbers, which are billed to the called party. The Commission will aggressively take action against those involved in such fraud. The Commission has the authority under the 1996 Act and its rules to take civil enforcement action against a payphone provider who deliberately violates the Commission's compensation rules by placing toll-free calls simply to obtain compensation from the carriers. More importantly, such activity may be fraud by wire and subject to criminal penalties.

19. The Commission has previously adopted a definition of ''payphone'' in the access code call compensation proceeding, although the definition is used only for purposes of the billing and collection of the compensation in that proceeding. It concluded that payphones appearing on the LEC-provided customer-owned, coin-operated telephone (''COCOT'') lists were payphones that are eligible for compensation. If a payphone provider does not subscribe to an identifiable payphone service, or if its payphone is omitted from the COCOT list in error, the provider is required to provide alternative verification information to the IXC paying compensation. The Commission concludes that this definition of ''payphone,'' regardless if the payphone in question is independently- or LEC-provided, will be sufficient for the payment of compensation as mandated by Section 276 and the instant proceeding. In addition, as discussed below, all payphones will be required to transmit specific payphone coding digits as a part of their automatic number identification (''ANI''), which will assist in identifying them to compensation payors. Beyond the immediate purposes of paying compensation, the Commission concludes that a payphone is any telephone made available to the public on a fee-per-call basis, independent of any other commercial transaction, for the purpose of making telephone calls, whether the telephone is coin-operated or is activated either by calling collect or using a calling card.

20. *Compensation Amount.* Because the Commission has established that the payphone marketplace has low entry and exit barriers and will likely become increasingly competitive, it concludes that the market (or the states, where there are special circumstances) is best able to set the appropriate price for payphone calls in the long term. The Commission concludes further that the appropriate per-call compensation amount ultimately is the amount the particular payphone charges for a local coin call, because the market will determine the fair compensation rate for those calls. For example, if the rate at a particular payphone is $.35, absent an agreement between the PSP and the carrier-payor for a different amount, then the PSP should receive $.35 for each compensable call (access code, subscriber 800, and directory assistance). If a rate is compensatory for local coin calls, then it is an appropriate compensation amount for other calls as well, because the cost of originating the various types of payphone calls are similar. Although the Commission tentatively concluded in the *NPRM* that PSPs should be compensated for their costs in originating calls, as these costs are measured by appropriate cost-based surrogates, the Commission now concludes that deregulated local coin rates are the best available surrogates for payphone costs and are superior to the cost surrogate data provided by the commenters.

21. The Commission concludes that the per-call compensation amount equal to the local coin rate is a default rate that will apply only in the absence of a negotiated agreement between the parties. PSPs, IXCs, subscriber 800 carriers, and intraLATA carriers may agree on an amount for some or all compensable calls that is either higher or lower than the local coin rate at a given payphone. In absence of an agreement, the PSP shall be entitled to receive compensation for compensable calls at a per-call rate equal to its local coin rate, which represents the market-based rate for a call at the payphone in question.

22. To allow the Commission to ascertain the status of competition in the payphone marketplace, it concludes that it should establish the default per-call rate for two years before leaving it to the market to set rate, absent any changes in the Commission's rules. More specifically, for the first year after the effective date of the rules adopted in this proceeding, IXCs will pay flat-rate compensation to PSPs. After the initial year, when per-call tracking capabilities will be in place, the Commission concludes that IXCs will be required to pay a default rate of $.35 per call, which is the local coin rate in four of the five states that have deregulated their local calling rates. The Commission concludes that the market-based rate in these states is the best evidence of a per-call compensation amount that will fairly compensate PSPs. Therefore, for the limited purpose of calculating compensation for PSPs for the first two years of compensation (one year of flat-rate and one year of per-call compensation), the Commission will use a default rate of $.35 per call, which is the rate in the majority of states that have allowed the market to determine the appropriate local coin rate. The carrier-payor and the PSP may agree to a compensation rate that is different, and, therefore, the default rate would not apply. For coinless payphones, which by definition do not have a local coin rate, the default rate will remain $.35 per call for as long as this rate is fairly compensable under Section 276(b)(1)(A).

23. Section 276(d) states that ''in this section, the term 'payphone service' means the provision of public or semi-public pay telephones * * *.'' Pursuant to this definition, all subsidies for semi-public payphones are terminated under Section 276(b)(1)(B), just as they are for public payphones, ''in favor of a compensation plan as specified in subparagraph (A)[.]'' Therefore, the Commission concludes that semi-public payphones are entitled to receive per-call compensation in the same manner as public payphones.

24. The Commission rejects the argument by four states that Section 276 applies only to payphones provided by the BOCs. While Section 276(a), which the states cite as support for their argument, applies only to the BOCs, as do Sections 276(b)(1)(C) and Section 276(b)(1)(D), the remainder of Section 276 applies to all payphones, regardless of their provider. Therefore, based on the plain language of the statute, the Commission concludes that Section 276 grants us the requisite authority to adopt rules that apply to all payphones, regardless of their provider, except where the language clearly applies only to the BOCs.

2. Entities Required To Pay Compensation

25. The Commission concludes that the primary economic beneficiary of payphone calls should compensate the PSPs. It concludes that the ''carrier-pays'' system for per-call compensation places the payment obligation on the primary economic beneficiary in the least burdensome, most cost effective manner. The Commission has previously adopted such an approach in the access code compensation proceeding, and the compensation

participants have created a payment system that is an appropriate model for this proceeding. In addition, under the carrier-pays system, individual carriers, while obligated to pay a specified per-call rate to PSPs, have the option of recovering a different amount from their customers, including no amount at all. The Commission concludes further that all IXCs that carry calls from payphones are required to pay per-call compensation.

26. The Commission concludes that it is the underlying, facilities-based carrier that should be required to pay compensation to the PSP in lieu of a non-facilities-based carrier that resells services, for example, to specific subscribers or to debit card users. Although the Commission has concluded that the primary economic beneficiary of payphone calls should bear the burden of paying compensation for these calls, it concludes that, in the interests of administrative efficiency and lower costs, facilities-based carriers should pay the per-call compensation for the calls received by their reseller customers. The Commission concludes further that the facilities-based carriers may recover the expense of payphone per-call compensation from their reseller customers as they deem appropriate, including negotiating future contract provisions that would require the reseller to reimburse the facilities-based carrier for the actual payphone compensation amounts associated with that particular reseller. While the Commission has not placed the burden of paying per-call compensation directly on resellers or debit card providers, it concludes that the underlying carrier must begin paying compensation on all compensable calls facilitated by its reseller and debit card customers and it is, in turn, permitted to impose the payphone compensation amounts on these customers.

3. Ability of Carriers To Track Calls From Payphones

27. Based on the information in the record, the Commission concludes that the requisite technology exists for IXCs to track calls from payphones. The Commission recognizes, however, that tracking capabilities vary from carrier to carrier, and that it may be appropriate, for an interim period, for some carriers to pay compensation for ''each and every completed intrastate and interstate call'' on a flat-rate basis until per-call tracking capabilities are put into place.

28. The Commission concludes further that, as stated in the *NPRM,* it is the responsibility of the carrier, whether it provides intraLATA or interLATA services, as the primary economic beneficiary of the payphone calls, to track the calls it receives from payphones, although the carrier has the option of performing the tracking itself or contracting out these functions to another party, such as a LEC or clearinghouse. In other words, while the Commission assigns the burden of tracking on the carrier receiving the call from a payphone, parties to a contract may find it economically advantageous to place this tracking responsibility on another party. The Commission declines to require LECs or PSPs to perform per-call tracking themselves. Neither LECs nor PSPs are the primary economic beneficiaries of payphone calls. The Commission concludes, however, that LECs, PSPs, and the carriers receiving payphone calls should be able to take advantage of each other's technological capabilities through the contracting process. To this end, the Commission concludes that no standardized technology for tracking calls is necessary, and that IXCs may use the technology of their choice to meet their tracking obligations.

29. The Commission concludes that each payphone should be required to generate 07 or 27 coding digits within the ANI for the carrier to track calls. Currently under the Commission's rules, LECs are required to tariff federally originating line screening (''OLS'') services that provide a discrete code to identify payphones that are maintained by non-LEC providers. The Commission concludes that LECs should be required to provide similar coding digits for their own payphones.

30. In view of the current difficulties in tracking such calls, the Commission concludes that a transition is warranted for requiring carriers to track compensable calls. Therefore, the Commission requires carriers to provide for tracking of all compensable calls they receive from payphones, through any arrangement they choose, as soon as possible, but no later than one year from the effective date of the rules adopted in this proceeding. Until that date, carriers must pay flat-rate compensation, as specified below.

31. The Commission recognizes that implementing a per-call tracking capability will require new investments for some carriers, particularly small carriers, but it concludes that the mandate of Section 276 that the Commission ensure a fair ''per call compensation plan'' for ''each and every completed intrastate and interstate call'' requires these carriers to provide tracking for calls for which they receive revenue, even though they previously did not have to compensate the PSP for many of these calls. The Commission concludes further that, by permitting carriers to contract out their per-call tracking responsibility, and by allowing a transition for tracking subscriber 800 calls, it will have taken the appropriate steps to minimize the per-call tracking burden on small carriers. In addition, the Commission concludes that, to parallel the obligation of the facilities-based carrier to pay compensation, the underlying facilities-based carrier has the burden of tracking calls to its reseller customers, and it may recover that cost from the reseller, if it chooses.

32. The Commission concludes that carriers should be required to initiate an annual verification of their per-call tracking functions to be made available for FCC inspection upon request, to ensure that they are tracking all of the calls for which they are obligated to pay compensation. The Commission requires this verification for a one-year period, the 1998 calendar year, and delegates to the Chief, Common Carrier Bureau, the authority to establish the form and content, if necessary, of the verification documentation of these per-call tracking capabilities. The Commission concludes that requiring carriers to maintain the appropriate records and certify as to the accuracy of both the data and the tracking methodology would facilitate the prompt and accurate payment of per-call compensation. The Commission also concludes that PSPs should be allowed to inspect this certification, apart from any proprietary network data. In addition, the Commission expects that the PSPs and carriers performing the tracking will work together to reconcile or explain any PSP data that are inconsistent with the annual certification.

4. Administration of Per-Call Compensation

33. The Commission concludes that it should adopt a direct-billing arrangement between IXCs and PSPs, once tracking capabilities are in place, that would build on the arrangement established in the access code call compensation proceeding, with the addition of the requirement that these carriers must send back to each PSP a statement indicating the number of toll-free and access code calls that each carrier has received from each of that PSP's payphones. This arrangement places the burden of billing and collecting compensation on the parties who benefit the most from calls from payphones—carriers and PSPs. As with the tracking of calls, carrier-payors are free to use clearinghouses, similar to

those that exist for access code call compensation, or to contract out the direct-billing arrangement associated with the payment of compensation.

34. The Commission requires that the carrier responsible for paying compensation file each year a brief report with the Common Carrier Bureau listing the total compensation paid to PSPs for intrastate, interstate, and international calls; the number of compensable calls carried by the carrier; and the number of payees. This requirement will apply to calendar year 1998, when tracking capabilities are in place and compensation is being paid on a per-call basis. The Commission concludes further that, once per-call compensation is routinely paid by IXCs, this reporting requirement will be terminated after the carriers have filed their reports for the 1998 calendar year. Carrier-payors should file their reports as soon as possible after the end of the calendar year, but no later than the end of the first quarter of the following year. To implement the reporting requirement, the Commission delegates to the Chief, Common Carrier Bureau, the authority to establish the form and content, if necessary, of the annual report listing the total amount of compensation paid to PSPs, including the authority to extend or limit the scope of this report.

35. The Commission concludes that it must establish minimal regulatory guidelines for the payphone industry regarding resolution of disputed ANIs to give LECs a greater incentive to provide accurate and timely verification of ANIs for independently provided payphones. While any party may file a complaint with the Commission about disputed ANIs, the Commission concludes that the better practice is for LECs who maintain the list of ANIs to work with both carrier-payors and PSPs to resolve disputes more efficiently and quickly before lodging a complaint with the Commission. The Commission also concludes that it should require that each LEC must submit to each carrier-payor on a quarterly basis a list of ANIs of all payphones in the LEC's service area (called the ''COCOT list'' in the access code call compensation proceeding).

36. The Commission concludes that the following guidelines will facilitate the proper verification of payphone ANIs by LECs. First, LECs must provide a list of payphone ANIs to carrier-payors within 30 days of the close of each compensation period (i.e., each quarter). Second, LECs must provide verification of disputed ANIs on request, in a timely fashion. Such verification data must be maintained and available for at least 18 months after the close of a compensation period. Third, once a LEC makes a positive identification of an installed payphone, the carrier-payor must accept claims for that payphone's ANI until the LEC provides information, on a timely basis, that the payphone has been disconnected. Fourth, a LEC must respond to all requests for ANI verification, even if the verification is a negative response. Carrier-payors are not required to pay compensation once the LEC verifies that the particular ANI is not associated with a COCOT line for which compensation must be paid. Fifth, carrier-payors should be able to refuse payment for compensation claims that are submitted long after they were due. Carriers should not refuse payment on timeliness grounds, however, for ANIs submitted by a PSP up to one year after the end of the period in question. Further, the period for a PSP to bring a complaint to the Commission based on an ANI disputed by the carrier-payor will not begin to accrue until the carrier-payor issues a final denial of the claim. The Commission concludes that the guidelines, as outlined above, will facilitate the proper verification of payphones without imposing undue burdens on LECs, PSPs, or carrier-payors.

37. Because a carrier-payor's administrative expenses are presumably reduced through the payment of compensation on a quarterly, as opposed to monthly, basis, the Commission concludes that the reasonable trade-off is that the carrier remains liable, as discussed above, for compensation claims that are submitted within one year of the end of the compensation period in question. The parties may themselves revisit this issue if they elect a shorter compensation period. Sprint argues that a carrier should be allowed to defer payments to individual PSPs until the amount due aggregates to $10 from that carrier to the particular PSP for all of its payphones. The Commission agrees and concludes that such a requirement would reduce the administrative expenses associated with the payment of compensation. If PSPs would like to charge interest on overdue payments from IXCs, as suggested by APCC, they should negotiate such a provision in their compensation agreement with the particular carrier.

38. The Commission concludes that the payment of compensation would be facilitated and some disputes avoided if LECs were required to state affirmatively on their bills to PSPs that the bills are for payphone service. The Commission concludes that LECs, who have knowledge that a particular phone line is used for a payphone, must indicate on that payphone's monthly bill that the amount due is for payphone service. The Commission also agrees with CompTel's suggestion that the registration of all payphones with a central resource or clearinghouse would reduce administrative costs for all parties and would avoid duplication of efforts. The Commission declines, however, to mandate the creation of a central resource or clearinghouse for compensation purposes, and believes that the parties themselves are better able to establish such a resource that would be directly connected to the payment of compensation.

5. Interim Compensation Mechanism

39. Because the IXCs required to pay compensation to PSPs are not required to track individual compensable calls until one year from the effective date of the rules adopted in this proceeding, the Commission concludes that PSPs should be paid monthly compensation on a flat rate by IXCs with annual toll revenues in excess of $100 million, beginning on the effective date of the rules adopted in this proceeding. Unlike the per-call compensation mechanism adopted in the *Report and Order,* the interim flat-rate compensation obligation applies to both facilities-based IXCs and resellers that have respective toll revenues of $100 million per year. This flat-rate monthly compensation will apply proportionally to individual IXCs, based on their respective annual toll revenues. For reasons of administrative convenience of the parties, the Commission concludes that it should model the interim mechanism adopted in the *Report and Order* on that set forth in the access code call compensation proceeding. In the access code compensation proceeding, CC Docket No. 91–35, the Commission excused several carriers from the obligation to pay flat-rate compensation for originating access code calls, because they certified that they were not providers of ''operator services,'' as defined by TOCSIA. The Commission notes that Section 276's requirement that it ensure fair compensation for ''each and every completed intrastate and interstate call,'' including access code calls, supersedes the compensation obligations established in CC Docket No. 91–35, including the waivers granted to AT&T and Sprint. Because Section 276 is the statutory authority for mandating per-call compensation for all compensable calls, including access code calls, the statutory exclusion in TOCSIA for those carriers that are not providers of ''operator services'' is no

longer a basis for being excused from the obligation to pay either the total flat-rate compensation amount established in the instant proceeding, or a portion thereof.

40. When the Commission adopted a compensation mechanism for interstate access code calls, it concluded that, because they did not involve use of a ''carrier-specific access code'' and were routed directly to an end user, subscriber 800 calls were not within the class of calls for which TOCSIA directed the Commission to consider compensation. The Commission, therefore, limited compensation to interstate ''access code calls.'' In the *Florida Payphone* decision, the United States Court of Appeals for the District of Columbia Circuit found no reason to distinguish between the routing of access code calls and subscriber 800 calls. Therefore, it reversed and remanded the case to the Commission to ''consider the need to prescribe compensation for subscriber 800 calls 'routed to providers of operator services that are other than the presubscribed provider of operator services.' '' For the limited purpose of calculating compensation for PSPs on a flat-rate basis until per-call compensation becomes mandatory the Commission will use a rate of $.35 per call, which is the rate in the majority of states that have allowed the market to determine the appropriate local coin rate.

41. The Commission next re-examines the average number of access code calls originated by a payphone per month. In 1992, the Commission found that the average was 15 calls. As summarized below, data on the record in the instant proceeding indicate that the average number of access code calls per month is now considerably higher. In addition, similar data show the volume of subscriber 800 calls generated by the average payphone.

42. Based on the call volume data provided by the PSPs, the Commission concludes that, for purposes of calculating flat-rate compensation, that the average payphone originates a combined total of 131 access code calls and subscriber 800 calls per month. When 131 calls per month is multiplied by the $.35 compensation amount, the monthly flat-rate compensation amount is $45.85. The Commission concludes that this $45.85 flat-rate amount must be paid by carriers, proportionally to their annual toll revenues, to PSPs. This flat-rate obligation applies to access code calls and subscriber 800 calls originated on or after the effective date of the rules adopted in this proceeding. PSPs that are affiliated with LECs will not be eligible for this interim compensation until the first day following their reclassification and transfer of payment equipment along with the termination of subsidies, as discussed below.

B. Reclassification of Incumbent LEC-Owned Payphones

43. In the foregoing Part, the Commission establishes rules and guidelines to ensure that PSPs are fairly compensated for calls originating at their payphones. For certain PSPs—those who are LECs—the new compensation arrangement can be implemented only upon the discontinuance of the regulatory system under which they now recover their costs of providing payphone service. In this Part, the Commission describes the necessary steps for the LECs' transition to the new compensation framework, and sets a schedule for the LECs' implementing actions.

44. Section 276(b)(1)(B) directs the Commission to ''discontinue the intrastate and interstate carrier access charge payphone service elements and payments in effect on such date of enactment, and all intrastate and interstate payphone subsidies from basic exchange and exchange access revenues, in favor of a [per-call] compensation plan[.]'' Currently, incumbent LEC payphones, classified as part of the network, recover their costs from Carrier Common Line (CCL) charges assessed on those carriers that connect with the incumbent LEC. In order to comply with Section 276(b)(1)(B) by removing payphone costs from the CCL charge and all intrastate and interstate payphone subsidies from basic exchange and exchange access revenues, the Commission adopts requirements on: (1) the prospective classification of incumbent LEC payphones as Customer Premises Equipment (CPE); (2) the transfer of incumbent LEC payphone equipment assets from regulated to nonregulated status; (3) the termination of access charge compensation and all other subsidies for incumbent LEC payphones; and (4) the classification of AT&T payphones.

1. Classification of LEC Payphones as CPE

i. CPE Deregulation

45. The Commission concludes that to best effectuate the 1996 Act's mandate that access charge payphone service elements and payphone subsidies from basic exchange and exchange access revenues be discontinued, incumbent LEC payphones should be treated as deregulated and detariffed CPE. The Commission determined in *Computer II* that CPE should be deregulated and detariffed to ensure that the costs associated with regulated services are separated from the competitive provision of the equipment used in conjunction with those services. The Commission concluded that CPE should be unbundled from its underlying transmission service in order to prevent improper cross-subsidization. Consistent with this prior finding, it concludes that LEC payphones must be treated as unregulated, detariffed CPE in order to ensure that no subsidies are provided from basic exchange and exchange access revenues or access charge payphone service elements as required by the Act.

ii. Unbundling of Payphone Services

46. The Commission concludes, pursuant to *Computer II*, Section 201, 202, and 276 of the Act, and previous CPE decisions, that incumbent LECs must offer individual central office coin transmission services to PSPs under nondiscriminatory, public, tariffed offerings if the LECs provide those services for their own operations. Under *Computer II*, all carriers must unbundle basic transmission services from CPE. Moreover, Section 202 of the Act prohibits a carrier from discriminating unreasonably in its provision of basic service. The Commission concludes that incumbent LECs must provide coin service so competitive payphone providers can offer payphone services using either instrument-implemented ''smart payphones'' or ''dumb'' payphones that utilize central office coin services, or some combination of the two in a manner similar to the LECs. Because the incumbent LECs have used central office coin services in the past, but have not made these services available to independent payphone providers for use in their provision of payphone services, the Commission requires that incumbent LEC provision of coin transmission services on an unbundled basis be treated as a new service under the Commission's price cap rules. Because incumbent LECs may have an incentive to charge their competitors unreasonably high prices for these services, the Commission concludes that the new services test is necessary to ensure that central office coin services are priced reasonably. Incumbent LECs not currently subject to price cap regulation must submit cost support for their central office coin services, pursuant to Sections 61.38, 61.39, or 61.50(i) of the Commission's rules. Incumbent LECs must file tariffs with the Commission for these services no later than January 15, 1997. To the extent that this requirement precludes

the BOCs from complying with the *Computer II, Computer III,* and *ONA* network information disclosure requirements, the Commission waives the notice period in order to ensure that these services are provided on a timely basis consistent with the other deregulatory requirements of this order. Pursuant to this waiver, network information disclosure on the basic network payphone services must be made by the BOCs by January 15, 1997.

47. The Commission concludes that tariffs for payphone services must be filed with the Commission as part of the LECs' access services to ensure that the services are reasonably priced and do not include subsidies. This requirement is consistent with the Section 276 prescription that all subsidies be removed from payphone operations. Accordingly, the Commission concludes that *Computer III* tariff procedures and pricing are more appropriate for basic payphone services provided by LECs to other payphone providers. Pursuant to Section 276(c), any inconsistent state requirements with regard to this matter are preempted.

iii. Other LEC Payphone Services

48. The Commission concludes that incumbent LECs should provide certain other services to other payphone providers if they provide those services to their own payphone operations. These services must be made available by the LEC or its affiliate to other payphone providers on a comparable basis in order to ensure that other payphone providers do not receive discriminatory service from the LECs once LEC payphones are deregulated, and to ensure that other payphone providers can compete with LEC payphone operations. The Commission concludes that fraud protection, special numbering assignments, and installation and maintenance of basic payphone services should be available to other providers of payphone services on a nondiscriminatory basis. Validation services are required by another proceeding. Regarding billing and collection services, the Commission concludes that if a LEC provides basic, tariffed payphone services that will only function in conjunction with billing and collection services from the LEC, the LEC must provide the billing and collection services it provides to its own payphone operations for these services to independent payphone providers on a nondiscriminatory basis. The Commission expects this requirement to apply, for example, in situations where coin services require the LEC to monitor coin deposits and such information is not otherwise available to third parties for billing and collection. It adopts this requirement to ensure that when a LEC has structured its payphone services in a way that they could not operate without the LECs billing and collection services, those services will be available to other payphone providers on the same basis they are available to the LEC.

iv. Registration and Demarcation Point for Payphones

49. The Commission amends its Part 68 rules to provide for the registration of central-office-implemented coin payphones to enable independent payphone providers as well as the LECs to utilize ''dumb'' payphones. Under the *Coin Registration Order,* 49 FR 27763 (July 6, 1984), and current Part 68 rules, only instrument-implemented payphones can be registered for connection to the network. Amending the Commission's rules enables independent payphone providers to have the same choices as LECs in providing payphone services. Accordingly, the Commission adopts amendments to Section 68.2(a)(1) and Section 68.3 of the Commission's rules to facilitate registration of both instrument-implemented and central-office-implemented payphones. The Commission grandfathers existing LEC payphones from the Commission's revised Part 68 requirements, unless the basic functionality in the payphones is changed. The Commission requires incumbent LECs to submit proposed interconnection requirements to effectuate such interconnection within 90 days of the effective date of this order. The California Payphone Association (CPA) filed before the Commission a Petition for Rule Making requesting that Section 68.2(a)(1) of the rules be amended to allow for the registration of all coin-operated telephones and that the Commission re-examine and clarify its interpretation of Section 68.2(a)(1). The Commission notes that its decision in the Report and Order addresses the relief requested in the CPA petition. The *Report and Order* also effectively grants a petition filed by the Public Telephone Council to treat payphones as CPE, and resolves the issues raised in RM 8723 regarding exclusion of public payphones from end user access charges.

50. Consistent with the Commission's objective of treating incumbent LEC and independent payphone providers' payphones in a similar manner, the Commission concludes that the demarcation point must be the same as incumbent LECs use for independent payphone providers today. Accordingly, the demarcation for all new LEC payphones must be consistent with the minimum point of entry, demarcation point standards for other wireline services. The Commission grandfathers the location of all existing LEC payphones in place on the effective date of this order because of the difficulty and cost of moving these payphones to meet the Commission's new demarcation point requirements. Similarly, the Commission does not require that network interfaces be placed for existing LEC payphones unless these payphones are substantially refurbished, for example, upgraded from dumb to smart payphones or replaced.

2. Reclassification or Transfer of Payphone Equipment to Nonregulated Status

51. The Commission's nonstructural safeguards include the cost allocation rules and affiliate transactions rules adopted in the *Joint Cost Order.* Under those rules, the BOCs and other incumbent LECs must classify each of their activities as regulated or nonregulated in accordance with the Commission's requirements. The Commission now requires that the BOCs and other incumbent LECs, subject to the Commission's joint cost rules, classify their payphone operations as nonregulated for Part 32 accounting purposes. The Commission notes, however, that the BOCs or other incumbent LECs are free to provide these services using structurally separate affiliates if they choose to do so. Therefore, the discussion below will address two possible approaches a carrier may take in reclassifying its payphone activities as nonregulated: (1) A carrier may maintain its payphone assets on the carrier's books but treat the assets as nonregulated, or (2) a carrier may transfer its payphone assets to a separate affiliate engaged in nonregulated activities.

i. Specific Assets Reclassified or Transferred

52. The payphone assets to be reclassified or transferred include all facilities related to payphone service, including associated accumulated depreciation and deferred income tax liabilities. The Commission, however, does not include as payphone assets to be reclassified or transferred the loops connecting the payphones to the network, the central office ''coin-service,'' or operator service facilities supporting incumbent LEC payphones because these are part of network equipment necessary to support basic telephone services.

ii. Accounting Treatment for Assets Reclassified or Transferred

53. Whether a carrier should account for the transfer or reclassification of the payphone assets from regulated to nonregulated status at ''fair market value'' or the net book value of the assets is determined on whether a carrier maintains the assets in its regulated Part 32 accounts or instead transfers the payphone assets to a separate affiliate or an operating division within the carrier that is treated as an affiliate.

54. Carriers that do not transfer the payphone assets to a separate affiliate make no reclassification accounting entries to their Part 32 regulated accounts. The reclassification of these assets to nonregulated status is accomplished instead through the operation of Part 64 cost allocation rules. Accordingly, the Commission concludes that payphone investment in Account 32.2351, Public telephone terminal equipment, and any other assets used in the provision of payphone service, along with the associated accumulated depreciation and deferred income tax liabilities should be directly assigned or allocated to nonregulated activities pursuant to cost allocation rules. LECs should establish whatever Part 64 cost pools are needed and should file revisions to their cost allocations manuals within sixty (60) days prior to the effective date of the change.

55. Carriers that transfer their payphone assets to either a separate affiliate or an operating division that has no joint and common use of assets or resources with the LEC and maintains a separate set of books in accordance with Section 32.23(b) of the Commission's rules must account for the transfer according to the affiliate transactions rules of Section 32.27(c) which require that the transfer be recorded at the higher of fair market value or cost less all applicable valuation reserves (net book cost). Fair market value has been defined as ''the price at which the property would change hands between a willing buyer and a willing seller, neither being under any compulsion to buy or sell and both having reasonable knowledge of relevant facts.'' The Commission concludes, that in instances when the transfer of payphone assets is governed by Section 32.27(c), it is appropriate that the going concern value associated with the payphone business be taken into consideration in determining fair market value. Such going concern value should include intangible assets such as location contracts that add value to the payphone business. These intangible assets would be considered in the theoretical purchase price negotiated by a willing buyer and seller. The Commission does not believe, however, that the intangible asset value of BOC or LEC brand names should be included in the determination of going concern or fair market value because a BOC or a LEC would not transfer the right to use its brand name to a third party willing buyer.

56. The difference in accounting treatment for payphone assets either reclassified as nonregulated pursuant to the Commission's Part 64 cost allocation rules or transferred to a separate affiliate and accounted for in accordance with the Commission's Part 32 affiliate transactions rules stems primarily from the fact that in one instance there is no transfer, only a reallocation of assets to nonregulated status, and in the other instance, there has been an actual transfer. In addition, in the first instance the Commission's rules are designed to promote fair cost allocation between regulated and nonregulated activities; in the second instance, the Commission's rules are designed to protect against cross-subsidies between separate companies by capturing any appreciated value of assets transferred on the books of the carrier.

iii. Other Matters

57. The Commission requires the LECs to reclassify any pay telephone investments recorded in Account 32.2351, Public telephone terminal equipment, and other assets used in the provision of payphone service, along with the associated accumulated depreciation and deferred income tax liabilities, from regulated to nonregulated status pursuant to the Commission's Part 64 and Part 32 rules by April 15, 1997 when the associated revised tariffs are effective. The Commission thus agrees with Ameritech that it should adopt its tentative conclusion that a phase-in period is unnecessary.

3. Termination of Access Charge Compensation and Other Subsidies

58. In the telephone network, payphones, as well as all other telephones, are connected to the local switch by means of a subscriber line. The costs of the subscriber line that are allocated to the interstate jurisdiction are recovered through two separate charges: a flat-rate SLC assessed upon the end-user customer who subscribes to local service; and a per-minute CCL charge assessed upon IXCs that recovers the balance of the interstate subscriber line costs not recovered through the SLC. LEC payphone costs are also included in the CCL charge. The CCL charge, however, applies to interstate switched access service that is unrelated to payphone service costs. While independent payphone providers are required to pay the SLC for the loop used by each of their payphones, LECs have not been required to pay this charge because the subscriber lines connected to LEC payphones have been recovered entirely through the CCL charge.

59. The Commission concludes that to implement Section 276 (b)(1)(B) of the 1996 Act, incumbent LECs must reduce their interstate CCL charges by an amount equal to the interstate allocation of payphone costs currently recovered through those charges. LECs subject to the price cap rules would treat this as an exogenous cost change to the Common Line basket pursuant to Section 61.45(d) of the Commission's rules. The incumbent LECs' residential SLC is limited to $3.50 per month and their multi-line business SLC is currently subject to a $6.00 per month cap. Those LECs with interstate subscriber line costs that exceed this amount recover a portion of the interstate costs of subscriber lines through the CCL charge. The issue of the appropriate interstate SLC has been referred to a Federal-State Joint Board.

60. Incumbent LECs today generally recover payphone costs allocated to the interstate jurisdiction through the per-minute carrier CCL charge they assess on IXCs and other interstate access customers for originating and terminating interstate calls. The incumbent LEC assesses the independent payphone provider a SLC (at the multi-line business rate) to recover the payphone common line costs associated with that phone. In the case of competitive payphones, an independent payphone provider recovers its payphone costs out of the revenue it receives from end users, premises owners, and OSPs to whom its payphones are presubscribed. The 1996 Act mandates that the Commission ''discontinue the intrastate and interstate carrier access charge payphone service elements and payments * * * and all intrastate and interstate subsidies from basic exchange and exchange access revenues[.]''

61. Accordingly, the Commission adopts rules that provide for the removal from regulated intrastate and interstate rate structures of all charges that recover the costs of payphones (*i.e.*, the costs of payphone sets, not including the costs of the lines connecting those sets to the public switched network, which, like the lines

connecting competitive payphones to the network, will continue to be treated as regulated). Therefore, the Commission concludes that incumbent LECs must file revised CCL tariffs with the Common Carrier Bureau no later than January 15, 1997 to reduce their interstate CCL charges by an amount equal to the interstate allocation of payphone costs currently recovered through those charges, scheduled to take effect April 15, 1997. LECs subject to the price cap rules must treat this as an exogenous cost change to the Common Line basket pursuant to Section 61.45(d)(1)(v) of the Commission's rules. Incumbent LECs must identify and report accounts that contain costs attributable to their payphone operations. Incumbent LECs must identify specific cost pools and allocators that are required to capture the nonregulated investment and expenses associated with their payphone operations. LECs must file this information with the Common Carrier Bureau by January 15, 1997.

62. LECs that file tariffs pursuant to Section 61.38 or Section 61.39, rate-of-return regulation, or Section 61.50, optional incentive regulation, must file tariffs to revise interstate CCL rates to remove the payphone investment and any other assets used in the provision of payphone service along with the accumulated depreciation and deferred income tax liabilities from the common line costs recovered through those rates. As stated previously, these LECs must reclassify payphone assets from regulated to nonregulated activity pursuant to Part 64 rules. Expenses incurred after payphones are deregulated should be classified as nonregulated expenses. The CCL rate reduction must account for overhead costs assigned to common line costs as a result of payphone investment and expenses. The Commission requires these LECs to recalculate their CCL rates, using the same data and methods they used to develop their current CCL rates, except those calculations should exclude payphone costs.

63. Price cap LECs are also required to revise their CCL rates, using the following method to remove payphone costs from their CCL rates. First, price cap LECs should develop a common line revenue requirement using ARMIS costs for calendar year 1995. Second, price cap LECs are required to develop a payphone cost allocator equal to the payphone costs in Section 69.501(d) divided by total common line costs, based on 1995 ARMIS data. Each LEC is required to reduce its PCI in the common line basket by this payphone cost allocator minus one.

64. The Commission requires, pursuant to the mandate of Section 276(b)(1)(B), incumbent LECs to remove from their intrastate rates any charges that recover the costs of payphones. Revised intrastate rates must be effective no later than April 15, 1997. Parties did not submit state-specific information regarding the intrastate rate elements that recover payphone costs. States must determine the intrastate rates elements that must be removed to eliminate any intrastate subsidies within this time frame.

65. Finally, the Commission concludes that, to avoid discrimination among payphone providers, the multiline business SLC must apply to subscriber lines that terminate at both LEC and competitive payphones. It concludes that the removal of payphone costs from the CCL and the payment or imputation of a SLC to the subscriber line that terminates at a LEC nonregulated payphone will result in the recovery of LEC payphone costs on a more cost-causative basis consistent with the requirements of the 1996 Act. No action the Commission takes in the Report and Order affects the authority of states to address the state ratemaking implications of reclassification or transfer of payphone assets.

4. Deregulation of AT&T Payphones

66. The Commission concludes that AT&T payphones must be deregulated, detariffed and treated as CPE. The Commission concluded that there is a competitive market for payphones, and, pursuant to Section 276, subsidies must be removed from payphone service. AT&T payphones have been treated like BOC payphones for regulatory purposes. It would be incongruous to deregulate payphone equipment owned by all other carriers except AT&T. The Commission concludes, therefore, that AT&T payphones must be removed from regulation and treated as independent PSPs' payphones. Accordingly, the Commission requires that AT&T follow the same procedures discussed above for valuing LEC payphone assets and transferring them to nonregulated status. After deregulation, AT&T payphones will be subject to the same requirements as independent payphone provider payphones.

67. With regard to the issue of bundling of transmission capacity and payphone CPE, the Commission does not have a sufficient record to revise, with regard to payphone CPE, the Commission's conclusion in the *Computer II* proceeding that there are public interest benefits in unbundling CPE from the underlying transmission service. The issue of IXC CPE bundling will be addressed in the *Interstate, Interexchange Marketplace* proceeding.

C. Nonstructural Safeguards for BOC Provision of Payphone Service

68. The foregoing parts establish a compensation arrangement that applies equally to the payphone operations of the BOCs, other LECs, AT&T and PSPs not affiliated with LECs. In this part, the Commission addresses certain operating requirements that are imposed only on the BOCs' payphone operations.

69. Section 276(b)(1)(C) directs the Commission to ''prescribe a set of nonstructural safeguards for Bell operating company payphone service to implement the provisions of paragraphs (1) and (2) of subsection (a), which safeguards shall, at a minimum, include the nonstructural safeguards equal to those adopted in the Computer Inquiry—III (CC Docket No. 90–623) proceeding[.]'' As referred to in Section 276(b)(1)(C), Section 276(a) provides that a BOC ''(1) shall not subsidize its payphone service directly or indirectly from its telephone exchange service operations or its exchange access operations; and (2) shall not prefer or discriminate in favor of its payphone service.''

a. Nonstructural Safeguards

70. In addition to the accounting safeguards that the Commission will adopt with respect to payphone services in the accounting safeguards proceeding, it concludes that the *Computer III* and *ONA* nonstructural safeguards will provide an appropriate regulatory framework to ensure that BOCs do not discriminate or cross-subsidize in their provision of payphone service. The Commission and the BOCs have substantial experience in the application of these safeguards that will facilitate their use in the context of BOC payphone services. Pursuant to these requirements, the Commission notes that any basic services provided by a BOC to its payphone affiliate must be available on a nondiscriminatory basis to other payphone providers and that payphone providers may request additional unbundled payphone services through the 120 day ONA service request process. To ensure that the BOCs comply with the *Computer III* and *ONA* nonstructural separation requirements for the provision of payphone services, the Commission requires that, within 90 days following publication of a summary of the *Report and Order* in the Federal Register, BOCs must file CEI plans describing how they will comply with the *Computer III* unbundling, CEI parameters, accounting requirements, CPNI requirements as

modified by Section 222 of the 1996 Act, network disclosure requirements, and installation, maintenance, and quality nondiscrimination requirements. Except for the Commission's Part 64 cost allocation rules and Part 32 affiliate transaction rules, the Commission declines to apply the *Computer III* nonstructural safeguards to other LECs.

b. BOC CEI Plans

71. The Commission requires that each BOC file, within 90 days following publication of a summary of the *Report and Order* in the Federal Register, an initial CEI plan describing how it intends to comply with the CEI equal access parameters and nonstructural safeguards for the provision of payphone services. In *Computer III,* CEI plans have been an integral part of ensuring that BOCs do not discriminate in providing basic underlying services to enhanced services providers. The Commission likewise requires the filing of CEI plans for payphone services, even though the Commission has traditionally only required such plans for the BOC provision of enhanced services, to ensure that the BOCs provide payphone services in a nondiscriminatory manner and consistent with other *Computer III* and *ONA* requirements. Finally, the Commission concludes that this requirement is consistent with the requirement in Section 276 that the Commission establish safeguards, at a minimum, ''equal to those adopted in the Computer III Inquiry.''

72. In a CEI plan, a BOC must describe how it intends to comply with the CEI ''equal access'' parameters for the specific payphone service it intends to offer. The CEI equal access parameters include: interface functionality; unbundling of basic services; resale; technical characteristics; installation, maintenance, and repair; end user access; CEI availability; minimization of transport costs; and availability to all interested customers or enhanced service providers.

73. In its CEI plan, a BOC must explain how it will unbundle basic payphone services. Thus, a BOC must indicate how it plans to unbundle, and associate with a specific rate element in a tariff, the basic services and basic service functions that underlie its provision of payphone service. Nonproprietary information used by the BOC in providing the unbundled basic services will be made available as part of CEI. In addition, any options available to the BOC in the provision of such basic services or functions would be included in the unbundled offerings.

74. A BOC also must explain in its CEI plan how it will comply with the CPNI requirements. The Commission has continued to require compliance with the *Computer III* and *ONA* CPNI requirements that are not inconsistent with Section 222 of the 1996 Act, which was immediately effective. In the *CPNI NPRM,* the Commission is currently examining a carrier's obligations under the CPNI provisions of the 1996 Act.

75. BOCs must comply with the *Computer III* and *ONA* network information disclosure requirements. The BOCs cannot design new network services or change network technical specifications to the advantage of their own payphones. Pursuant to these rules, the BOCs must disclose information about changes in their networks or new network services at two different points in time. First, disclosure must occur at the ''make/buy'' point: when a BOC decides to make for itself, or procure from an unaffiliated entity, any product whose design affects or relies on the network interface. Second, a BOC must publicly disclose technical information about a new service 12 months before it is introduced. If the BOC can introduce the service within 12 months of the make/buy point, it would make a public disclosure at the make/buy point. The public disclosure, however, must not occur less than six months before the introduction of the service.

76. In addition, BOCs must comply with the *Computer III* and *ONA* requirements regarding nondiscrimination in the quality of service, installation, and maintenance. BOCs must indicate in their CEI plans how they will comply with these requirements. The Commission does not impose any new continuing reporting requirement because BOCs are already subject to reporting requirements pursuant to *Computer III* and *ONA.* BOCs must report on payphone services as they do for other basic services.

D. Ability of BOCs to Negotiate With Location Providers on the Presubscribed Interlata Carrier

77. Section 276(b)(1)(D) of the 1996 Act directs the Commission to eliminate the court-ordered competitive barrier prohibiting the BOCs from participating in the selection of presubscribed interLATA carriers to their payphones, unless the Commission finds such activity to be contrary to the public interest.

78. Payphone providers, both PSPs and independent LECs, compete in the market for payphone services by offering location providers a commission on coin and 0+ traffic originating from the payphones located on the location providers' premises. In turn, these payphone service providers earn revenues by contracting for the presubscription of 0+ traffic originating from their payphones. The 1996 Act directs the Commission to provide similar rights to the BOCs, unless the Commission determines it is not in the public interest. The Commission concludes that it would not be contrary to the public interest to allow the BOCs to negotiate with location providers with respect to the selecting and contracting for the interLATA carriers presubscribed to their payphones. The Commission first finds that the payphone industry is competitive and characterized by low barriers to entry which would act to prevent the BOCs from exercising market power in the provision of payphone services. The Commission explains that, although the BOCs currently have a large share of the payphone services market, there are also thousands of competitors. These competitors range in size from very small entities with only a handful of payphones, to the major long distance companies. The Commission finds that the existence of these many small competitors demonstrates that entry is relatively easy and does not require investment or scale levels that would deter many potential competitors. The Commission also concludes that any ability that the BOCs might have to raise prices to end users above competitive levels is severely restricted by the ability of end users to dial around the presubscribed interLATA carrier. The Commission explains that a sustained effort by the BOCs to pass on monopoly price levels to consumers would induce more end users to take advantage of this alternative.

79. The Commission also determines that the nonstructural and accounting safeguards required with respect to the BOCs' payphone operations are sufficient to deter the BOCs from improperly subsidizing those operations from their local access services or discriminating in the provision of local access services to the detriment of their payphone competitors. As discussed previously, the Commission is applying all *Computer III* and *ONA* nonstructural and accounting safeguards to the BOCs' provision of payphone services, and requiring that any basic services provided by a BOC to its own payphone operations to be available on a nondiscriminatory basis to other payphone providers. The Commission concludes that these safeguards provide an appropriate regulatory framework to ensure that BOCs do not engage in improper subsidization or discriminate

in the provision of services required by their payphone competitors. For these reasons, and because it finds that the statutory language reflects a Congressional determination that structural separation of the BOCs' payphone operations from their core business is neither necessary nor appropriate, the Commission declines to impose such structural separation on the BOCs' payphone business. The Commission does require that the nonstructural and accounting safeguards established pursuant to Section 276(b)(1)(C) of the 1996 Act be in place before the BOCs are allowed to participate in the interLATA presubscription process for their payphones. Specifically, the *Report and Order* requires a BOC to submit and receive approval of an initial CEI plan filed pursuant to Section 276(b)(1)(C) as a precondition to being authorized to engage in the conduct authorized by Section 276(b)(1)(D).

80. The *Report and Order* recognizes that location providers are to retain the ultimate decision-making authority in determining interLATA services in connection with the choice of payphone providers. The Commission finds that if strong competition is established in the payphone industry, location providers will be assured of the ultimate choice of the interLATA carrier serving payphones on their premises through the selection of PSPs. The Commission concludes that competition in the payphone industry is sufficiently strong to ensure that location providers have freedom of choice concerning the interLATA carrier for payphones on their premises. The Commission emphasizes, however, that a location provider's ability to choose should be protected from unjust and unreasonable practices which seek to foreclose meaningful choice. Such practices as unreasonable interference with pre-existing agreements between location providers and PSPs or carriers, or conduct which is unduly coercive of the location provider's right to choose the carrier for payphones on its premises, may constitute violations of Section 201 of the Communications Act.

81. The Commission rejects the argument that the presubscription rights specified in Section 276(b)(1)(D) constitute the provision of interLATA service subject to the restrictions of Sections 271 and 272 of the 1996 Act. The Commission finds that the statutory language authorizing the BOCs to ''select and contract with, the carriers that carry interLATA calls from their payphones,'' grants the BOCs no more than the right to participate as a contractual intermediary between a location provider and a third-party interLATA carrier. Such conduct does not amount to the provision of interLATA telecommunications service addressed under Sections 271 and 272. The Commission does find, however, that, for purposes of Section 276, resale by a BOC of interLATA service for its in-region presubscribed payphones lies outside of the specific rights granted by Section 276(b)(1)(D) of the 1996 Act, and is subject to the requirements set forth in Section 271(b).

82. The Commission affirms its tentative conclusion in the *NPRM* that the 1996 Act grandfathers all contracts in force between location providers and PSPs or interLATA or intraLATA carriers which were in force and effect as of February 8, 1996.

E. Ability of Payphone Service Providers to Negotiate With Location Providers on the Presubscribed Intralata Carrier

83. The Commission affirms its tentative conclusion in the *NPRM* that all PSPs should have the right to negotiate with location providers concerning the intraLATA carriers presubscribed to their payphones. The Commission also concludes that state regulations which require the routing of intraLATA calls to the incumbent LEC are inconsistent with this provision of the 1996 Act. Pursuant to the specific authority in Section 276(c), the Commission concludes that all such state requirements are therefore preempted by the Commission's regulations.

84. The Commission also affirms its tentative conclusion in the *NPRM* that intraLATA carriers presubscribed to payphones should be required to meet the Commission's minimum standards for routing and handling emergency calls. By mandating the application of minimum standards to intraLATA carriers presubscribed to payphones, the Commission seeks to ensure that individuals receive timely and proper assistance when they rely on payphones for 0- and 911 emergency calls.

F. Establishment of Public Interest Payphones

85. Section 276(b)(2) of the 1996 Act directs the Commission to ''determine whether public interest payphones, which are provided in the interest of public health, safety, and welfare, in locations where there would otherwise not be a payphone, should be maintained, and if so, ensure that such public interest payphones are supported fairly and equitably.'' The Commission concludes that there is a need to ensure the maintenance of public interest payphones that serve public policy interests in health, safety, and welfare, in locations where there might not otherwise be a payphone as a result of the operation of the market. The Commission explains that all payphones serve the public interest by providing access to basic communications services. The Commission expresses particular concern about the role served by payphones in providing access to emergency services, especially in isolated locations and areas with low levels of residential phone penetration. The Commission recognizes, however, the potential that a freely competitive marketplace may not provide for payphones in locations where they serve important public policy objectives, but which, for various reasons, may not be economically self-supporting. With the elimination of subsidies which have helped to support such payphones in the past, as directed by the 1996 Act, it is possible that many of these payphones could disappear absent the availability of alternative methods to ensure their existence.

86. The Commission concludes that primary responsibility for administering and funding public interest payphone programs should be left to the states, subject to guidelines adopted by the Commission. The Commission finds that the states are better equipped than the Commission to respond to geographic and socio-economic factors affecting the need for such payphones that are too diverse to be effectively addressed on a national basis.

87. While leaving broad discretion to the states with respect to the implementation of public interest payphone programs, the Commission finds that the adoption of certain minimum guidelines is necessary to meet its statutory obligation to ensure that public interest payphones are funded fairly and equitably. The Commission adopts as a definition of ''public interest payphone,'' a payphone which (1) fulfills a public policy objective in health, safety, or public welfare, (2) is not provided for a location provider with an existing contract for the provision of a payphone, and (3) would not otherwise exist as a result of the operation of the competitive marketplace. The Commission concludes that reliance on the public interest payphone provisions of the 1996 Act should be limited to instances where a payphone location serves a strong public interest that would not be fulfilled by the normal operation of the market. The Commission also concludes that the statutory language requires a national guideline that companies providing public interest payphones be fairly

compensated for the cost of such services. The states have discretion with respect to funding their respective public interest payphone programs, so long as the funding mechanism, (1) ''fairly and equitably'' distributes the cost of such a program, and (2) does not involve the use of subsidies prohibited by Section 276(b)(1)(B) of the 1996 Act. State programs supporting public interest payphones are also subject to the provision of Section 253(b) of the 1996 Act which requires that such a program be implemented on a ''competitively neutral basis.'' The Commission specifically recognizes that states may address the need for public interest payphones by adopting appropriate rules in conjunction with their state universal service plans pursuant to Section 254(f) of the 1996 Act. The Commission finds that the implementation of a public interest payphone program is consistent with the goals of universal service.

88. Also in furtherance of its statutory responsibility under Section 276(b)(2), the Commission directs each state to review whether it has adequately provided for public interest payphones in a manner consistent with the *Report and Order*. Each state is required, within two years of the date of issuance of the *Report and Order*, to evaluate whether it needs to take any measures to ensure that payphones serving important public interests will continue to exist in light of the elimination of subsidies and other competitive provisions established pursuant to Section 276 of the 1996 Act, and that any existing programs are administered and funded consistent with the Commission's rules. The Commission also provides that interested parties may file petitions with the Commission challenging state requirements that are believed to be inconsistent with Section 276(b)(2) or guidelines adopted by the Commission implementing the provisions of that Section.

G. Other Issues

1. Dialing Parity

89. The Commission affirms its tentative conclusion in the *NPRM* that the benefits of dialing parity adopted pursuant to Section 251(b)(3) of the 1996 Act should extend to all payphone location providers. The Commission finds that dialing parity is an important element in fostering vigorous competition in the payphone industry, as in the local exchange and long distance industry, by ensuring that each customer has the freedom and the flexibility to choose among different carriers for different services without the burden of dialing access codes. The Commission concludes that the technical and timing requirements established pursuant to Section 251(b)(3), and Section 271(c)(2)(B), should apply equally to payphones.

90. The Commission also concludes that the unblocking of carrier access codes mandated by the Telephone Operator Consumer Services Improvement Act of 1990 (''TOCSIA''), Section 226 of the Act, and the Commission's rules for interstate calls, should also apply to intrastate (including local) access code calls. Given the existence of compensation and the pro-competitive purpose of Section 276 of the 1996 Act, and the absence of any technical limitations, the Commission finds that unblocked access for all access code calls from payphones is required.

2. Letterless Keypads

91. The Commission affirms its tentative conclusion in the *NPRM* that the use of letterless keypads on payphones violates both TOCSIA and the 1996 Act. The Commission finds that an exclusively numeric payphone keypad defeats a caller's attempt to reach its OSP of choice through the use of commonly-used ''vanity'' access sequences such as AT&T's ''1–800–CALL-ATT'' and MCI's ''1–800–COLLECT.'' Such access sequences, which can be easily remembered by consumers, require the presence of both alphabetic and numeric characters on payphone keypads. The Commission finds no plausible purpose for letterless keypads other than to restrict access to a non-presubscribed carrier. The Commission determines that it has authority to take enforcement action, including forfeitures, if such devices are used, and orders that OSPs may not pay commissions to PSPs utilizing such devices.

3. Oncor Petition

92. The Commission denies the petition of Oncor Communications, Inc., filed August 7, 1995, requesting that the Commission prescribe compensation for public payphone premises owners and presubscribed OSPs. The Commission invited comment on Oncor's petition by Public Notice released September 12, 1995. The Commission finds that the presubscribed OSP incurs no costs when a consumer makes an access code call from a payphone, and it would be inequitable to require any party to compensate the presubscribed OSP because the caller chose not to use it. The Commission also notes that the rules adopted in the *Report and Order* will ensure that PSPs are fairly compensated for calls that originate from their payphones, and market forces will ensure that the PSPs fairly compensate premises owners.

III. Conclusion

93. In the *Report and Order*, the Commission establishes procedures that will ensure that all payphone service providers are fairly compensated for every completed intrastate, interstate and international call, except for those calls excepted by statute, and adopts interim compensation until the new compensation procedures are effective. The Commission also establishes procedures that ensure that all subsidies from basic exchange and exchange access revenues are removed simultaneous with the LECs' receipt of compensation for calls from LEC payphones. The Commission requires the BOCs to comply with certain nonstructural safeguards for their provision of payphone service, and allows them to negotiate with location providers for selecting and contracting with the carriers that provide interLATA service from their payphones. The *Report and Order* also sets forth guidelines for public interest payphones, and establishes guidelines for states to use in their proceedings for funding of such payphones.

IV. Ordering Clauses

94. Accordingly, pursuant to authority contained in Sections 1, 4, 201–205, 215, 218, 219, 220, 226, and 276 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154, 201–205, 215, 218, 219, 220, 226, and 276, *it is ordered* that the policies, rules, and requirements set forth herein *are adopted*.

95. *It is further ordered*, that 47 CFR Part 64, Sections 64.1301 and 64.1340, *are amended* as set forth below, effective November 6, 1996, and that 47 CFR Part 64, Sections 64.1330 and 64.703 *are amended* as set forth below, effective December 16, 1996.

96. *It is further ordered*, that 47 CFR Part 64, Section 64.1301 is removed and Sections 64.1300, 64.1310 and 64.1320, *are amended* as set forth below, effective October 7, 1997.

97. *It is further ordered*, that 47 CFR Part 68, *is amended* as set forth below, effective April 15, 1997.

98. *It is further ordered*, that local exchange carriers *shall reclassify* their payphone assets and related expenses to nonregulated status on April 15, 1997.

99. *It is further ordered*, that carriers required to file a cost allocation manual pursuant to 47 CFR Section 64.903 or by Commission order *shall file* revisions to their manuals implementing the

reclassification required herein no later than February 14, 1997.

100. *It is further ordered*, that local exchange carriers *shall file* tariff revisions required by paras. 180 to 187 of the *Report and Order* on January 15, 1997, to be effective April 15, 1997.

101. *It is further ordered*, the Bell Operating Companies *are granted* waivers of the time requirements of the *Computer II* and the *Computer III* network disclosure requirements in order to provide basic network payphone services by April 15, 1997. Pursuant to this waiver, network disclosure notification for these basic network payphone services must be filed no later than January 15, 1997.

102. *It is further ordered*, that the Bell Operating Companies *shall file* CEI plans for the provision of payphone service not later than Janaury 6, 1997.

103. *It is further ordered*, that the waivers of Section 64.1301 of the Commission's Rules granted to AT&T and Sprint in the proceedings referenced in para. 119 of the *Report and Order are revoked*, effective 30 days after publication of a summary of this *Report and Order* in the Federal Register.

104. *It is further ordered*, that the proceedings initiated by our *Memorandum Opinion and Order on Further Reconsideration and Second Further Notice of Proposed Rulemaking* in CC Docket 91–35, 60 FR 48957 (September 21, 1995), Policies and Rules Concerning Operator Service Access and Pay Telephone Compensation, 10 FCC Rcd 11457 (1995), *are terminated*.

105. *It is further ordered*, that the July 18, 1988 Petition of the Public Telephone Council for a declaratory ruling that BOC Payphones should be treated as CPE *is dismissed as moot*.

106. *It is further ordered*, that the August 7, 1995 Petition of Oncor Communications, Inc. Requesting Compensation for Competitive Payphone Premises Owners and Presubscribed Operator Services Providers *is denied*.

107. *It is further ordered*, that the proceedings entitled Amendment of Section 69.2 (m) and (ee) of the Commission's Rules to Include Independent Public Payphones Within the ''Public Telephone'' Exemption from End User Common Line Access Charges, RM 8723, *are terminated*.

108. *It is further ordered*, that the December 28, 1989 Petition of the California Payphone Association *is dismissed as moot*.

109. *It is further ordered*, that the provisions set forth in Section 1.4 of the Commission's rules establishing the date of public notice for this *Report and Order are waived*, and petitions for reconsideration *shall be filed* within 30 days of release of this document, and oppositions to the petitions must be filed within seven (7) days after the date for filing the petitions for reconsideration. For purposes of this proceeding, Section 1.106(h) of the Commission's Rules *is waived*, and the Commission will not accept replies to oppositions.

List of Subjects

47 CFR Part 64

Communications common carriers, Payphone compensation, Operator service access, Telephone.

47 CFR Part 68

Administrative practice and procedure, Communications common carrier, Communications equipment, Labeling, Reporting and record keeping requirements, Telephone.

Federal Communications Commission.

Shirley S. Suggs,

Chief, Publications Branch.

Rule Changes

Parts 64 and 68 of Title 47 of the Code of Federal Regulations are amended as follows:

PART 64—MISCELLANEOUS RULES RELATING TO COMMON CARRIERS

1. Effective November 6, 1996, the authority citation for Part 64 is revised to read as follows:

Authority: 47 U.S.C. 154, unless otherwise noted. Interpret or apply 47 U.S.C. 201, 218, 226, 228, 276 unless otherwise noted.

2. Effective December 16, 1996, § 64.703(b) is amended by removing the word ''and'' at the end of paragraph (b)(2), and by redesignating paragraph (b)(3) as paragraph (b)(4); and adding a new paragraph (b)(3) to read as follows:

§ 67.703 Consumer information.

* * * * *

(b) * * *

(3) In the case of a pay telephone, the local coin rate for the pay telephone location; and

* * * * *

3. Effective November 6, 1996, the heading of Subpart M of Part 64 is revised to read as follows:

Subpart M—Payphone Compensation

4. Effective November 6, 1996, § 64.1301 is amended by revising the first sentence of paragraph (a) and paragraph (b) to read as follows:

§ 64.1301 Competitive payphone compensation.

(a) Each payphone service provider eligible to receive compensation shall be paid $45.85 per payphone per month for originating access code and toll-free calls. * * *

(b) This compensation shall be paid by interexchange carriers (IXCs) that earn annual toll revenues in excess of $100 million, as reported in the FCC staff report entitled ''Long Distance Market Shares.'' Each individual IXC's compensation obligation shall be set in accordance with its relative share of toll revenues among IXCs required to pay compensation. For example, if total toll revenues of IXCs required to pay compensation is $50 billion, and one of these IXCs had $5 billion of total toll revenues, the IXC must pay $4.585 per payphone per month.

* * * * *

5. Effective December 16, 1996, § 64.1330 is added to subpart M to read as follows:

§ 64.1330 State review of payphone entry and exit regulations and public interest payphones.

(a) Each state must review and remove any of its regulations applicable to payphones and payphone service providers that impose market entry or exit requirements.

(b) Each state must ensure that access to dialtone, emergency calls, and telecommunications relay service calls for the hearing disabled is available from all payphones at no charge to the caller.

(c) Each state must review its rules and policies to determine whether it has provided for public interest payphones consistent with applicable Commission guidelines, evaluate whether it needs to take measures to ensure that such payphones will continue to exist in light of the Commission's implementation of Section 276 of the Communications Act, and administer and fund such programs so that such payphones are supported fairly and equitably. This review must be completed by September 20, 1998.

6. Effective November 6, 1996, § 64.1340 is added to read as follows:

§ 64.1340 Right to negotiate.

Unless prohibited by Commission order, payphone service providers have the right to negotiate with the location provider on the location provider's selecting and contracting with, and, subject to the terms of any agreement with the location provider, to select and contract with, the carriers that carry interLATA and intraLATA calls from their payphones.

7. Effective October 7, 1997, § 64.1300 is added to subpart M to read as follows:

§ 64.1300 Payphone compensation obligation.

(a) Except as provided herein, every carrier to whom a completed call from a payphone is routed shall compensate the payphone service provider for the call at a rate agreed upon by the parties by contract.

(b) The compensation obligation set forth herein shall not apply to calls to emergency numbers, calls by hearing disabled persons to a telecommunications relay service or local calls for which the caller has made the required coin deposit.

(c) In the absence of an agreement as required by paragraph (a) of this section, the carrier obligated to compensate the payphone service provider shall do so at a per-call rate equal to its local coin rate at the payphone in question.

(d) For the initial one-year period during which carriers are required to pay per-call compensation, in the absence of an agreement as required by paragraph (a) of this section, the carrier is obligated to compensate the payphone service provider at a per-call rate of $.35 per call. After this initial one-year period of per-call compensation, paragraph (c) of this section will apply.

§ 64.1301 [Removed]

8. Effective October 7, 1997, § 64.1301 is removed.

9. Effective October 7, 1997, section 64.1310 is added to read as follows:

§ 64.1310 Payphone compensation payment procedures.

(a) It is the responsibility of each carrier to whom a compensable call from a payphone is routed to track, or arrange for the tracking of, each such call so that it may accurately compute the compensation required by Section 64.1300(a).

(b) Carriers and payphone service providers shall establish arrangements for the billing and collection of compensation for calls subject to Section 64.1300(a).

(c) Local Exchange Carriers must provide to carriers required to pay compensation pursuant to Section 64.1300(a) a list of payphone numbers in their service areas. The list must be provided on a quarterly basis. Local Exchange Carriers must verify disputed numbers in a timely manner, and must maintain verification data for 18 months after close of the compensation period.

(d) Local Exchange Carriers must respond to all carrier requests for payphone number verification in connection with the compensation requirements herein, even if such verification is a negative response.

(e) A payphone service provider that seeks compensation for payphones that are not included on the Local Exchange Carrier's list satisfies its obligation to provide alternative reasonable verification to a payor carrier if it provides to that carrier:

(1) A notarized affidavit attesting that each of the payphones for which the payphone service provider seeks compensation is a payphone that was in working order as of the last day of the compensation period; and

(2) Corroborating evidence that each such payphone is owned by the payphone service provider seeking compensation and was in working order on the last day of the compensation period. Corroborating evidence shall include, at a minimum, the telephone bill for the last month of the billing quarter indicating use of a line screening service.

10. Effective October 7, 1997, § 64.1320 is added subpart M to read as follows:

§ 64.1320 Payphone compensation verification and reports.

(a) Carriers subject to payment of compensation pursuant to Section 64.1300(a) shall conduct an annual verification of calls routed to them that are subject to such compensation and file a report with the Chief, Common Carrier Bureau within 90 days of the end of the calendar year, provided, however, that such verification and report shall not be required for calls received after December 31, 1998.

(b) The annual verification required in this section shall list the total amount of compensation paid to payphone service providers for intrastate, interstate and international calls, the number of compensable calls received by the carrier and the number of payees.

PART 68—CONNECTION OF TERMINAL EQUIPMENT TO THE TELEPHONE NETWORK

11. The authority citation for Part 68 is revised to read as follows:

Authority: 47 U.S.C. 151, 154, 155, 201–5, 208, 215, 218, 226, 227, 303, 313, 314, 403, 404, 410, 602.

12. Effective April 15, 1997, § 68.2(a)(1) is revised to read as follows:

§ 68.2 Scope.

(a) * * *

(1) Of all terminal equipment to the public switched telephone network, for use in conjunction with all services other than party line service;

* * * * *

13. Effective April 15, 1997, § 68.3 is amended by adding the definitions of ''central-office implemented telephone'' and ''instrument implemented telephone'' in alphabetical order and removing the definitions of ''coin-implemented telephone'' and ''coin service'' to read as follows:

§ 68.3 Definitions.

* * * * *

Central-office implemented telephone: A telephone executing coin acceptance requiring coin service signaling from the central office.

* * * * *

Instrument-implemented telephone: A telephone containing all circuitry required to execute coin acceptance and related functions within the instrument itself and not requiring coin service signaling from the central office.

* * * * *

This Attachment will not be published in the Code of Federal Regulations.

ATTACHMENT—INTERIM COMPENSATION OBLIGATIONS

Company	1995 Total toll services revenues (dollar in millions)	Percent of total toll revenues	Amount per phone per month
AT&T Companies:			
AT&T Communications, Inc	$38,069	56.69	$25.9923406
Alascom, Inc	325	0.48	0.2219000
MCI Telecommunciations Corp	12,924	19.25	8.8241091
Sprint Communications Co	7,277	10.84	4.9685115
LDDS Worldcom	3,640	5.42	2.4852799

ATTACHMENT—INTERIM COMPENSATION OBLIGATIONS—Continued

Company	1995 Total toll services revenues (dollar in millions)	Percent of total toll revenues	Amount per phone per month
Frontier Companies:			
Allnet Comm. Svcs. dba Frontier Comm. Svcs	827	1.23	0.5646501
Frontier Communications Intl, Inc	309	0.46	0.2109757
Frontier Comm. of the North Central Region	133	0.20	0.0908083
Frontier Communications of the West, Inc	127	0.19	0.0867117
Cable & Wireless Communications, Inc	700	1.04	0.4779384
LCI International Telecom Corp	671	1.00	0.4581381
Excel Telecommunications, Inc	363	0.54	0.2478452
Telco Communications Group, Inc	215	0.32	0.1467954
Midcom Communications, Inc	204	0.30	0.1392849
Tel Save, Inc [9]	180	0.27	0.1228985
U.S. Long Distance, Inc	155	0.23	0.1058292
Vartex Telecom, Inc	125	0.19	0.0853461
General Communication, Inc	120	0.18	0.0819323
Business Telecom, Inc	115	0.17	0.0785185
Oncor Communications, Inc	111	0.17	0.0757874
The Furst Group, Inc	109	0.16	0.0744218
American Network Exchange, Inc	101	0.15	0.0689597
Total	67,153	100.00	45.85

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NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1815, 1816, 1852, and 1870

Rewrite of the NASA FAR Supplement (NFS)

AGENCY: Office of Procurement, National Aeronautics and Space Administration (NASA).

ACTION: Interim rule.

SUMMARY: Part 1815 is revised to delete the NASA-unique source selection procedures and established those in FAR 15.6 as the standard for NASA negotiated competitive acquisition, with appropriate supplementation; implement recent FAR changes resulting from provisions of the Federal Acquisition Streamlining Act (FASA) of 1994; and incorporate other acquisition streamlining procedures or delete unnecessary regulatory coverage, consistent with the NFS rewrite philosophy. Part 1816 is revised for the same reasons as above, as well as to clarify the relationship between cost-plus-award-fee (CPAF) contracting and performance based contracting (PBC). Subpart 1870.3 is deleted in its entirety. The numbering of NFS sections has been changed to indicate the exact section of the FAR being implemented or supplemented. Since the changes either conform NASA procedures to those of the FAR, implement FASA-related FAR changes, or affect acquisition procedures to the extent that immediate adoption is necessary, NASA is issuing the changes as an interim rule, with an effective date 30 days after publication.

DATES: This rule is effective November 6, 1996. All comments on this interim rule should be in writing and must be received by November 6, 1996.

ADDRESSES: Bruce King, Code HC, NASA Headquarters, 300 E Street, SW., Washington, DC 20546–0001; Tom O'Toole, Code HC, NASA Headquarters, 300 E Street, SW., Washington, DC 20546–0001.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas O'Toole, (202) 358–0478; Mr. Bruce King, (202) 358–0461.

SUPPLEMENTARY INFORMATION:

Background

The National Performance Review urged agencies to streamline and clarify their regulations. The NFS rewrite initiative was established to pursue these goals by conducting a section by section review of the NFS to verify its accuracy, relevancy, and validity. The NFS will be rewritten in blocks of parts and upon completion of all parts, the NFS will be reissued in a new edition.

Impact

NASA certifies that this regulation 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.*). This rule does not impose any reporting or record keeping requirements subject to the Paperwork Reduction Act.

List of Subjects in 48 CFR Parts 1815, 1816, 1852, and 1870

Government procurement.

Deidre A Lee,

Associate Administrator for Procurement.

Accordingly, 48 CFR Parts 1815, 1816, 1852, and 1870 are amended as follows:

2. Part 1815 is revised to read as follows:

PART 1815—CONTRACTING BY NEGOTIATION

Subpart 1815.4—Solicitation and Receipt of Proposals and Quotations

Sec.

1815.405 Solicitations for information or planning purposes.
1815.405–70 Draft requests for proposals.
1815.406 Preparing requests for proposals (REPs) and requests for quotations (FRQs).
1815.406–2 Part I—The Schedule.
1815.406–5 Part IV—Representations and instructions.
1815.406–70 Page limitations.
1815.406–71 Installation reviews.
1815.406–72 Headquarters reviews.
1815.407 Solicitation provisions.
1815.407–70 NASA solicitation provisions.
1815.408 Issuing solicitations.
1815.408–70 Blackout notices.
1815.412 Late proposals, modifications, and withdrawals of proposals.
1815.412–70 Broad agency announcements (BAAs), Small Business Innovative Reearch (SBIR), and Small Business Technology Transfer (STTR) solicitations.
1815.413 Disclosure and use of information before award.
1815.413–2 Alternate II.

1815.413–270 Appointing non-Government evaluators as special Government employees.

Subpart 1815.5—Unsolicited Proposals

1815.502 Policy.
1815.503 General.
1815.504 Advance guidance.
1815.506 Agency procedures.
1815.506–70 Relationship of unsolicited proposals to NRAs.
1815.508 Prohibitions.
1815.508–70 NASA prohibitions.
1815.509 Limited use of data.
1815.509–70 Limited use of proposals.
1815.570 Foreign proposals.

Subpart 1815.6—Source Selection

1815.601 Definitions.
1815.602 Applicability.
1815.605–70 Evaluation factors and subfactors.
1815.608 Proposal evaluation.
1815.608–70 Identification of unacceptable proposals.
1815.608–71 Evaluation of a single proposal.
1815.609 Competitive range.
1815.610 Written or oral discussions.
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Authority 42 U.S.C. 2473(c)(1)

Subpart 1815.4—Solicitation and Receipt of Proposals and Quotations

1815.405 Soliciations for information or planning purposes.

1815.405–70 Draft requests for proposals.

(a) Except for acquisitions described in 1815.602(b), contracting officers shall issue draft requests for proposals (DRFPs) for all competitive negotiated acquisitions expected to exceed $1,000,000 (including all options or later phases of the same project). DRFPs shall invite comments from potential offerors on all aspects of the draft solicitation, including the requirements, schedules, proposal instructions, and evaluation approaches. Potential offerors should be specifically requested to identify unnecessary or inefficient requirements. When considered appropriate, the statement of work or the specifications may be issued in advance of other solicitation sections.

(b) Contracting officers shall plan the acquisition schedule to include adequate time for issuance of the DRFP, potential offeror review and comment, and NASA evaluation and disposition of the comments.

(c) When issuing DRFPs, potential offerors should be advised that the DRFP is not a solicitation and NASA is not requesting proposals.

(d) Whenever feasible, contracting officers should include a summary of the disposition of significant DRFP comments with the final RFP.

(e) The procurement officer may waive the requirement for a DRFP upon written determination that the expected benefits will not be realized given the nature of the supply or service being acquired. The DRFP shall not be waived because of poor or inadequate planning.

1815.406 Preparing requests for proposals (RFPs) and requests for quotations (RFQs).

1815.406–2 Part I—The Schedule. (NASA supplements paragraph (c))

(c) To the maximum extent practicable, requirements should be defined as performance based specifications/statements of work that focus on required outcomes or results, not methods of performance or processes.

1815.406–5 Part IV—Representations and instructions. (NASA supplements paragraph (b))

(b) The information required in proposals should be kept to the minimum necessary for the source selection decision. Although offerors should be provided the maximum flexibility in developing their proposals, contracting officers shall specify any information and standard formats required for the efficient and impartial evaluation of proposals.

1815.406–70 Page limitations.

(a) Technical and contracting personnel will mutually agree on page limitations for their respective portions of an RFP. Unless approved in writing by the procurement officer, the page limitation for the contracting portion of an RFP (all sections except Section C, Description/ specifications/work statement) shall not exceed 150 pages, and the page limitation for the technical portion (Section C) shall not exceed 200 pages. Attachments to the RFP count as part of the section to which they relate. In determining page counts, a page is defined as one side of a sheet, 8½″ x 11″, with at least one inch margins on all sides, using not smaller than 12 characters per inch or equivalent type. Foldouts count as an equivalent number of 8½″ x 11″ pages. The metric standard format most closely approximating the described standard 8½″ x 11″ size may also be used.

(b) Page limitations shall also be established for proposals submitted in competitive acquisitions. Accordingly, technical and contracting personnel will mutually agree on page limitations for each portion of the proposal. Unless a different limitation is approved in writing by the procurement officer, the total initial proposal, excluding title pages, tables of content, and cost/price information, shall not exceed 500 pages using the page definition of 1815.406–70(a). Firm page limitations shall also be established for Best and Final Offers (BAFOs), if requested. The appropriate BAFO page limitations should be determined by considering the complexity of the acquisition and the extent of any written or oral discussions. The same BAFO page limitations shall apply to all offerors. Pages submitted in excess of the specified limitations for the initial proposal and BAFO will not be evaluated by the Government and will be returned to the offeror.

1815.406–71 Installation reviews.

(a) Installations shall establish procedures to review all RFPs before release. When appropriate given the

complexity of the acquisition or the number of offices involved in solicitation review, centers should consider use of a single review meeting, called a Solicitation Review Board (SRB), as a streamlined alternative to the serial or sequential coordination of the solicitation with reviewing offices. The SRB is a meeting in which all offices having review and approval responsibilities discuss the solicitation and their concerns. Actions assigned and changes required by the SRB shall be documented.

(b) When source evaluation board (SEB) procedures are used in accordance with 1815.612–70, the SEB shall review and approve the RFP prior to issuance.

1815.406–72 Headquarters reviews.

For RFPs requiring Headquarters review and approval, the procurement officer shall submit ten copies of the RFP to the Associate Administrator for Procurement (Code HS). Any significant information relating to the RFP or the planned evaluation methodology that are not included in the RFP itself should also be provided.

1815.407 Solicitation provisions. (NASA supplements paragraphs (c) and (d))

(c)(6) The provision at FAR 52.215–10, Late Submissions, Modifications, and Withdrawals of Proposals shall not be used in solicitations for the Small Business Innovation Research (SBIR) or Small Business Technology Transfer programs, or for broad agency announcements listed in 1835.016. See instead 1815.407–70(a).

(d)(4) The contracting officer shall insert FAR 52.215–16 Alternate II in all competitive negotiated solicitations.

1815.407–70 NASA solicitation provisions.

(a) The contracting officer shall insert the provision at 1852.215–73, Late Submissions, Modifications, and Withdrawals of Proposals (AO, SBIR, and STTR Programs), in lieu of the provision at FAR 52.215–10 in Announcements of Opportunity issued pursuant to subpart 1870.1 and in Small Business Innovation Research (SBIR) and Small Business Technology Transfer solicitations. (See 1815.412).

(b) The contracting officer shall insert a provision substantially as stated at 1852.215–74, Alternate Proposals, in competitive requests for proposals if receipt of alternate proposals would benefit the Government.

(c) The contracting officer shall insert the provision at 1852.215–75, Expenses Related to Offeror Submissions, in all requests for proposals.

(d) The contracting officer shall insert the provision at 1852.215–77, Preproposal/Pre-bid Conference, in competitive requests for proposals and invitations for bids where the Government intends to conduct a preproposal or pre-bid conference. Insert the appropriate specific information relating to the conference.

(e) The contracting officer shall insert the clause at 1852.214–71, Grouping for Aggregate Award, in solicitations when it is in the Government's best interest not to make award for less than specified quantities solicited for certain items or groupings of items. Insert the item numbers and/or descriptions applicable for the particular acquisition.

(f) The contracting officer shall insert the clause at 1852.214–72, Full Quantities, in solicitations when award will be made only on the full quantities solicited.

(g) The contracting officer shall insert the provision at 1852.215–81, Proposal Page Limitations, in all competitive requests for proposals.

(h) The contracting officer shall insert the provision at 1852.215–82, Offeror Oral Presentations, in competitive requests for proposals when the Government intends to allow offerors to make oral presentations prior to commencement of the Government's formal evaluation.

1815.408 Issuing solicitations.

1815.408–70 Blackout notices.

(a) Upon release of the formal RFP, the Contracting Officer shall direct all personnel associated with the acquisition to refrain from communicating with prospective offerors and to refer all inquiries to the Contracting Officer or other authorized representative. This procedure is commonly known as a ''blackout notice'' and shall not be imposed prior to release of the RFP. The notice may be issued in any format (e.g., letter or electronic) appropriate to the complexity of the acquisition.

(b) Blackout notices are not intended to terminate all communication with offerors. Contracting officers should continue to provide information as long as it does not create an unfair competitive advantage or reveal offeror proprietary data.

1815.412 Late proposals, modifications, and withdrawals of proposals.

1815.412–70 Broad agency announcements (BAAs), Small Business Innovative Research (SBIR), and Small Business Technology Transfer (STTR) solicitations.

For BAAs listed in 1835.016, SBIR Phase I and Phase II solicitations, and STTR solicitations—

(a) Proposals, or modifications to them, received from qualified firms after the latest date specified for receipt may be considered if a significant reduction in cost to the Government is probable or if there are significant technical advantages, as compared with proposals previously received. In such cases, the project office shall investigate the circumstances surrounding the submission of the late proposal or modification, evaluate its content, and submit written recommendations and findings to the selection official or a designee as to whether there is an advantage to the Government in considering the proposal.

(b) The selection official or a designee shall determine whether to consider the proposal.

(c) Offerors may withdraw proposals any time before award, provided the conditions in paragraph (b) of the provision at 1852.215–73, Late Submissions, Modifications, and Withdrawals of Proposals (AO, SBIR, and STTR Programs), are satisfied.

1815.413 Disclosure and use of information before award.

1815.413–2 Alternate II.

(NASA supplements paragraphs (a), (e), and (f))

The alternate procedures at FAR 15.413–2 shall be used for NASA acquisitions in lieu of those prescribed at FAR 15.413–1. These procedures, as implemented by this section, apply both before and after award.

(a) During evaluation proceedings, NASA personnel participating in any way in the evaluation may not reveal any information concerning the evaluation to anyone not also participating, and then only to the extent that the information is required in connection with the evaluation. When non-NASA personnel participate, they shall be instructed to observe these restrictions.

(e) The notice at FAR 15.413–2(e) shall be placed on the cover sheet of all proposals, whether solicited or unsolicited. (See 1805.402 regarding release of the names of firms submitting offers.)

(f)(i) Except as provided in paragraph (f)(ii) of this section, the procurement officer is the approval authority to disclose proposal information outside the Government. This authorization may be granted only after compliance with FAR 37.2 and 1837.204, except that the determination of nonavailability of Government personnel required by FAR 37.2 is not required for disclosure of proposal information to JPL employees.

(ii) Proposal information in the following classes of proposals may be

disclosed with the prior written approval of a NASA official one level above the NASA program official responsible for overall conduct of the evaluation. The determination of nonavailbility of Government personnel required by FAR 37.2 is not required for disclosure in these instances.

(A) NASA Announcements of Opportunity proposals;

(B) Unsolicited proposals;

(C) NASA Research Announcement proposals;

(D) SBIR and STTR proposals.

(iii) The written approvals required by paragraphs (f) (i) and (ii) of this section shall be provided to the contracting officer before the release of the proposal information. As a minimum, the approval shall:

(A) Identify the precise proposal information being released;

(B) Identify the person receiving the proposal information and evidence of their appointment as a special government employee or a statement of the applicable exception (see 1815.413–270);

(C) Provide a justification of the need for disclosure of the proposal information to the non-Government evaluator(s); and

(D) Provide a statement that a signed ''Agreement and Conditions for Evaluation of Proposals,'' in accordance with paragraph (f)(2) of this section, will be obtained prior to release of the proposal to the evaluator.

(iv) If JPL personnel, in evaluating proposal information released to them by NASA, require assistance from non-JPL, non-Government evaluators, JPL must obtain written approval to release the information in accordance with paragraphs (f)(i) and (f)(ii) of this section.

(f)(2) The NASA official approving the disclosure of any proposal information to a non-Government evaluator, including employees of JPL, shall, prior to such disclosure, require each non-Government evaluator to sign the following ''Agreement and Conditions for Evaluation of Proposals.''

Agreement and Conditions for Evaluation of Proposals, October 1996

(1) The recipient agrees to use proposal information for NASA evaluation purposes only. This limitation does not apply to information that is otherwise available without restrictions to the Government, another competing contractor, or the public.

(2) The recipient agrees that the NASA proposal cover sheet notice (FAR 15.413–2(e) and NFS 1815.413–2(e)), and any notice that may have been placed on the proposal by its originator, shall be applied to any reproduction or abstract of any proposal information furnished.

(3) Upon completion of the evaluation, the recipient agrees to return all copies of proposal information or abstracts, if any, to the NASA office that initially furnished the proposal information for evaluation.

(4) Unless authorized in writing by the NASA official releasing the proposal information, the recipient agrees not to contact either the business entities originating the proposals or any of their employees, representatives, or agents concerning any aspect of the proposal information or extracts covered by this agreement.

(5) The recipient agrees to review his or her financial interests relative to the entities whose proposal information NASA furnishes for evaluation. At any time the recipient becomes aware that he or she or a person with a close personal relationship (household family members, business partners, or associates) has or acquires a financial interest in the entities whose proposal information is subject to this agreement, the recipient shall immediately advise the NASA official releasing the proposal information, protect the proposal information, and cease evaluation activities pending a NASA decision resolving the conflict of interest.

Signature: _____

Name typed or printed: _____

Date: _____

[End of agreement]

1815.413–270 Appointing non-Government evaluators as special Government employees.

(a) Except as provided in paragraph (c) of this section, non-Government participants in proposal evaluation proceedings, except employees of JPL, shall be appointed as special Government employees.

(b) Appointment as a Special Government employee is a separate action from the approval required by paragraph 1815.413–2(f) and may be processed concurrently. Appointment as a special Government employee shall be made by:

(1) The NASA Headquarters personnel office when the release of proposal information is to be made by a NASA Headquarters office; or

(2) The Field Installation personnel office when the release of proposal information is to be made by the Field Installation.

(c) Non-Government evaluators need not be appointed as special Government employees when they evaluate:

(1) NASA Announcements of Opportunity proposals;

(2) Unsolicited proposals;

(3) NASA Research Announcement proposals; and

(4) SBIR and STTR proposals.

Subpart 1815.5—Unsolicited Proposals

1815.502 Policy. (NASA supplements paragraphs (1) and (2))

(1) An unsolicited proposal may result in the award of a contract, a grant, a cooperative agreement, or other agreement. If a grant or cooperative agreement is used, the NASA Grant and Cooperative Agreement Handbook (NPG 5800.1) applies.

(2) Renewal proposals, (i.e., those for the extension or augmentation of current contracts) are subject to the same FAR and NFS regulations, including the requirements of the Competition in Contracting Act, as are proposals for new contracts.

1815.503 General. (NASA supplements paragraph (e))

(e) NASA will not accept for formal evaluation unsolicited proposals initially submitted to another agency or to the Jet Propulsion Laboratory (JPL) without the offeror's express consent.

1815.504 Advance guidance. (NASA supplements paragraph (b))

(b) The Headquarters Office of Procurement (Code HK) is responsible for preparing for public use a brochure titled ''Guidance for the Preparation and Submission of Unsolicited Proposals,'' which shall be provided without charge by the Office of Procurement and other NASA officials in response to requests for proposal submission information. A deviation is required for use of any modified or summarized version of the brochure or for alternate means of general dissemination of unsolicited proposal information. Code HK is responsible for internal distribution of the brochure.

1815.506 Agency procedures. (NASA supplements paragraph (a))

(a)(i) NASA Headquarters and each NASA field installation shall designate an organizational entity as its unsolicited proposal coordinating office for receiving and coordinating the handling and evaluation of unsolicited proposals.

(ii) Each installation shall establish procedures for handling proposals initially received by other offices within the installation. Misdirected proposals shall be forwarded by the coordinating office to the proper installation. Field installation coordinating offices are also responsible for providing guidance to potential offerors regarding the appropriate NASA officials to contact for general mission-related inquiries or other preproposal discussions.

(iii) Coordinating offices shall keep records of unsolicited proposals received and shall provide prompt

status information to requesters. These records shall include, at a minimum, the number of unsolicited proposals received, funded, and rejected during the fiscal year; the identity of the offerors; and the office to which each was referred. The numbers shall be broken out by source (large business, small business, university, or nonprofit institution).

1815.506–70 Relationship of unsolicited proposals to NRAs.

An unsolicited proposal for a new effort or a renewal, identified by an evaluating office as being within the scope of an open NRA, shall be evaluated as a response to that NRS (see 1835.016–70), provided that the evaluating office can either:

(a) State that the proposal is not at a competitive disadvantage or

(b) Give the offeror an opportunity to amend the unsolicited proposal to ensure compliance with the applicable NRA proposal preparation instructions. If these conditions cannot be met, the proposal must be evaluated separately.

1815.508 Prohibitions. (NASA supplements paragraph (b))

(b) FAR 15.508(b) shall not apply to NASA; see instead 1815.508–70.

1815.508–70 NASA prohibitions.

Information (data) in unsolicited proposals furnished to the Government is to be used for evaluation purposes only. Disclosure outside the Government for evaluation is permitted only to the extent authorized by, and in accordance with procedures in, FAR 15.413–2 and 1815.413–2.

1815.509 Limited use of data.

FAR 15.509 shall not apply to NASA. See instead 1815.509–70.

1815.509–70 Limited use of proposals.

(a) The provision at FAR 52.215.12, Restriction on Disclosure and Use of Data, is applicable to unsolicited proposals.

(b) If an unsolicited proposal is received with a more restrictive legend than made applicable by paragraph (a) of this section, the procedures of FAR 15.413–2(c) apply.

(c) Upon receipt in the coordinating office, the Government notice in FAR 15.413–2(e) shall be placed on the cover sheet of all unsolicited proposals.

(d) Unsolicited proposals shall be evaluated outside the Government only to the extent authorized by, and in accordance with the procedures prescribed in, FAR 15.413–2(f) and 1815.413–2.

(e) If a request is made under the Freedom of Information Act for any information contained in an unsolicited proposal, the procedures of FAR 15.413–2(g) apply.

§ 1815.570 Foreign proposals.

Unsolicited proposals from foreign sources are subject to NMI 1362.1, Initiation and Development of International Cooperation in Space and Aeronautical Programs.

Subpart 1815.6—Source Selection

§ 1815.601 Definitions. (NASA supplements paragraph (1) and (2))

(1) The source selection authority (SSA) is the Agency official responsible for proper and efficient conduct of the source selection process and for making the final source selection decision. The SSA has the following responsibilities:

(i) Approve the evaluation factors, subfactors, and elements, the weight of the evaluation factors and subfactors, and any special standards of responsibility (see FAR 9.104–2) prior to release of the RFP, or delegate this authority to appropriate management personnel;

(ii) Appoint the source selection team. However, when the Administrator will serve as the SSA, the Official-in-Charge of the cognizant Headquarters Program Office will appoint the team; and

(iii) Provide the source selection team with appropriate guidance and special instructions to conduct the evaluation and selection procedures.

(2) The SSA shall be established at the lowest reasonable level for each acquisition. For acquisitions designated as Headquarters selections, the SSA will be identified as part of the Master Buy Plan process (see 1807.71).

§ 1815.602 Applicability. (NASA supplements paragraphs (a) and (b))

(a)(i) Except as indicated in paragraph (b) of this section, NASA competitive negotiated acquisitions shall be conducted as follows:

(A) Acquisitions of $50 million or more—in accordance with FAR 15.6 and this subpart.

(B) Other acquisitions—in accordance with FAR 15.6 and this subpart except section 1815.612–70.

(ii) Estimated dollar values of acquisitions shall include the values of multiple awards, options, and later phases of the same project.

(b) FAR 15.6 and this subpart are not applicable to acquisitions conducted under the following procedures:

(i) MidRange (see part 1871).

(ii) Announcements of Opportunity (see 1870.102, App. I).

(iii) NASA Research Announcements (see 1835.016–70 and 1870.203, App. I).

(iv) The Small Business Innovative Research (SBIR) program and the Small Business Technology Transfer (STTR) pilot program under the authority of the Small Business Act (15 U.S.C. 638).

(V) Architect and Engineering (A&E) services (see FAR 36.6 and 1836.6).

1815.605–70 Evaluation factors and subfactors.

(a) Typically, NASA establishes three evaluation factors: Mission Suitability, Cost/Price, and Relevant Experience and Past Performance. Evaluation factors may be further defined by subfactors. Although discouraged, subfactors may be further defined by elements. Evaluation subfactors and any elements should be structured to identify significant discriminations, or ''key swingers''—the essential information required to support a source selection decision. Too many subfactors and elements undermine effective proposal evaluation. All evaluation subfactors and any elements should be clearly defined to avoid overlap and redundancy.

(b) Mission Suitability factor. (1) This factor indicates the merit or excellence of the work to be performed or product to be delivered. It includes, as appropriate, both technical and management subfactors. Mission Suitability shall be numerically weighted and scored on a 1000-point scale.

(2) The Mission Suitability factor may identify evaluation subfactors to further define the content of the factor. Each Mission Suitability subfactor shall be weighted and scored. The adjectival rating percentages in 1815.608(a)(3)(A) shall be applied to the subfactor weight to determine the point score. The number Mission Suitability subfactors is limited to four. The Mission Suitability evaluation subfactors and their weights shall be identified in the RFP.

(3) Although discouraged, elements that further define the content of each subfactor may be identified. Elements, if used, shall not be numerically weighted and scored. The total number of elements is limited to eight. Any Mission Suitability elements shall be identified in the RFP.

(4) For cost reimbursement acquisitions, the Mission Suitability evaluation shall also include the results of any cost realism analysis. The RFP shall notify offerors that the realism of proposed costs may significantly affect their Mission Suitability scores.

(c) *Cost/Price factor.* This factor evaluates the reasonableness and, if necessary, the cost realism, of proposed cost/prices. The Cost/Price factor is not numerically weighted or scored.

(d) *Relevant Experience and Past Performance factor.* (1) This factor indicates the relevant quantitative and qualitative aspects of each offeror's record of performing services or delivering products similar in size, content, and complexity to the requirements of the instant acquisition. The Relevant Experience and Past Performance factor is not numerically weighted or scored.

(2) The RFP shall instruct offerors to submit data (including data from relevant Federal, State, and local governments and private contracts) that can be used to evaluate their relevant experience and past performance. Typically, the RFP will require:

(i) A list of contracts similar in-size, content and complexity to the instant acquisition, showing each contract number, the type of contract, a brief description of the work, and a point of contact from the organization placing the contract. Normally, the requested contracts are limited to those received in the last three years. However, in acquisitions that require longer periods to demonstrate performance quality, such as hardware development, the time period should be tailored accordingly.

(ii) The identification and explanation of any cost overruns or underruns, completion delays, performance problems and terminations.

(3) The Contracting Officer may start collecting past performance data prior to proposal receipt. One method for initiating the past performance evaluation early is to request offerors to submit their past performance information in advance of the proposal due date. The RFP could also include a past performance questionnaire for offerors to send their previous customers with instructions to return the completed questionnaire to the Government. Failure of the offeror to submit its past performance information early or of the customers to submit the completed questionnaires shall not be a cause for rejection of the proposal nor shall it be reflected in the Government's evaluation of the offeror's past performance.

1815.608 Proposal evaluation. (NASA supplements paragraphs (a) and (b))

(a) Each proposal shall be evaluated to identify and document:

(i) Any failures to meet any terms and conditions of the RFP;

(ii) All strengths and weaknesses, classified as major or minor to further underscore discriminators among proposals;

(iii) The numerical score and/or adjectival rating of each Mission Suitability subfactor and for the Mission Suitability factor in total;

(iv) Cost realism, if appropriate;

(v) The adjectival rating of the Relevant Experience and Past Performance evaluation factor; and

(vi) Any technical, schedule, and cost risk. Risks may result from the offeror's technical approach, manufacturing plan, selection of materials, processes, equipment, etc., or as a result of the cost, schedule and performance impacts associated with these approaches. Risk evaluations must consider the probability of success, the impact of failure, and the alternatives available to meet the requirements. Risk assessments shall be considered in determining Mission Suitability strengths, weaknesses and numerical/adjectival ratings. Identified risk areas and the potential for cost impact shall be considered in the cost or price evaluation.

(1) Cost or price evaluation. (A) In accordance with 1815.804–1, cost or pricing data shall not be requested in competitive acquisitions. Only the minimal information other than cost or pricing data necessary to ensure price reasonableness and assess cost realism should be requested.

(B) When contracting on a firm fixed price basis, the contracting officer shall not request any cost information, unless proposed prices appear unreasonable or unrealistically low given the offeror's proposed approach and there are concerns that the contractor may default.

(C) When contracting on a basis other than firm fixed price, the contracting officer shall perform price and cost realism analyses to assess the reasonableness and realism of the proposed costs. A cost realism analysis will determine if the costs in an offeror's proposal are realistic for the work to be performed, reflect a clear understanding of the requirements, and are consistent with the various elements of the offeror's technical proposal. The analysis should include;

(*a*) The probable cost to the Government of each proposal, including any recommended additions or reductions in materials, equipment, labor hours, direct rates and indirect rates. The probable cost should reflect the best estimate of the cost of any contract which might result from that offeror's proposal.

(*b*) The differences in business methods; operating procedures, and practices as they impact cost.

(*c*) A level of confidence in the probable cost assessment for each proposal.

(D) The cost realism analysis may result in adjustments to Mission Suitability scores in accordance with the procedure described in 1815.608(a)(3)(B).

(E) The cost or price evaluation, specifically the cost realism analysis, often requires a technical evaluation of proposed costs. Contracting officers may provide technical evaluators a copy of the cost volume or relevant information from it to use in the analysis.

(2) Past performance evaluation. (A) The Relevant Experience and Past Performance evaluation assesses the contractor's performance under previously awarded contracts. It should evaluate the company, not the individuals, involved with contractor performance. Relevant Experience and Past Performance is not numerically scored, but is assigned an adjectival rating.

(B) The evaluation may be limited to specific areas of past performance considered most germane for the instant acquisition. It may include any or all of the items listed in FAR 42.1501, and/or any other aspects of past performance considered pertinent to the solicitation requirements or challenges. Regardless of the areas of past performance selected for evaluation, the same areas shall be evaluated for all offerors in that acquisition.

(C) The evaluation may consider past performance data provided by offerors and data from other sources. Questionnaires and interviews may be used to solicit assessments of the offeror's performance, as either a prime or subcontractor, from the offeror's previous customers.

(D) All pertinent information, including customer assessments and any offeror rebuttals, will be made part of the source selection records and included in the evaluation.

(iii) Firms without relevant experience or a past performance record shall not be given a proposal deficiency or weakness (see 1815.610) and shall be given a neutral rating. If the adjectival rating system of 1815.608(a)(3)(A) is used for the Relevant Experience and Past Performance factor, a rating of ''Good'' shall be assigned in such cases.

(3) Technical Evaluation. (A) Mission Suitability subfactors and the total Mission Suitability factor shall be evaluated using the following adjectival ratings, definitions and percentile ranges.

Adjectival rating	Definitions	Percentile range
Excellent	A comprehensive and thorough proposal of exceptional merit with one or more major strengths. No weaknesses or only minor weaknesses exist..	91–100.
Very Good	A proposal which demonstrates over-all competence. One or more major strengths have been found, and strengths outbalance any weaknesses that exist..	71–90.
Good	A proposal which shows a reasonably sound response. There may be strengths or weaknesses, or both. As a whole, weaknesses not off-set by strengths do not significantly detract from the offeror's response..	51–70.
Fair	A proposal that has one or more weaknesses. Weaknesses have been found that outbalance any strengths that exist..	31–50.
Poor	A proposal that has one or more major weaknesses that demonstrate a lack of overall competence or would require a major proposal revision to address..	0–30.

(B) When contracting on a cost reimbursement basis, the Mission Suitability evaluation shall reflect the results of any required cost realism analysis performed under the cost/price factor. A structured approach shall be used to adjust Mission Suitability scores based on the degree of assessed cost realism. An example of such an approach would:

(*a*) Establish a threshold at which Mission Suitability adjustments would start. The threshold should reflect the acquisition's estimating uncertainty (i.e., the higher the degree of estimating uncertainty, the higher the threshold);

(*b*) Use a graduated scale that proportionally adjusts a proposal's Mission Suitability score for its assessed cost realism;

(*c*) Affect a significant number of points in order to encourage realistic pricing.

(*d*) Calculate a Mission Suitability point adjustment based on the percentage difference between proposed and probable cost as follows:

Services	Hardware development	Point adjustment
+/−5 percent	+/−30 percent	0
+/−6 to 10 percent.	+/−31 to 40 percent.	−50
+/−11 to 15 percent.	+/−41 to 50 percent.	−100
+/−16 to 20 percent.	+/−51 to 60 percent.	−150
+/−21 to 30 percent.	+/−61 to 70 percent.	−200
+/− more than 30 percent.	+/− more than 70 percent.	−300

(b) The contracting officer is authorized to make the determination to reject all proposals received in response to a solicitation.

1815.608–70 Identification of unacceptable proposals.

(a) The contracting officer shall not complete the initial evaluation of any proposal when it is determined that the proposal is unacceptable because:

(1) It does not represent a reasonable initial effort to address itself to the essential requirements of the RFP or clearly demonstrates that the offeror does not understand the requirements;

(2) In research and development acquisitions, a substantial design drawback is evident in the proposal, and sufficient correction or improvement to consider the proposal acceptable would require virtually an entirely new technical proposal; or

(3) It contains major technical or business deficiencies or omissions or out-of-line costs which discussions with the offeror could not reasonably be expected to cure.

(b) The contracting officer shall document the rationale for discontinuing the initial evaluation of a proposal in accordance with this section.

1815.608–71 Evaluation of a single proposal.

(a) If only one proposal is received in response to the solicitation, the contracting officer shall determine if the solicitation was flawed or unduly restrictive and determine if the single proposal is an acceptable proposal. Based on these findings, the Source Selection Authority shall direct the contracting officer to:

(1) Award without discussions provided the contracting officer determines that adequate price competition exists (see FAR 15.804–1(b)(1)(ii));

(2) Award after negotiating a mutually acceptable contract. (The requirement for submission of cost or pricing data shall be determined in accordance with FAR 15.804–1); or

(3) Reject the proposal and cancel the solicitation.

(b) The procedure in 1815.608–71(a) also applies when the number of proposals equals the number of awards contemplated or when only one acceptable proposal is received.

1815.609 Competitive range. (NASA supplements paragraph (a))

(a) Proposals shall not be included in the competitive range when they do not have a reasonable chance of selection. To reduce unnecessary expenses to both offerors and NASA, a total of no more than three proposals shall be a working goal in establishing the competitive range. Field installations may establish procedures for approval of competitive range determinations commensurate with the complexity or dollar value of an acquisition.

1815.610 Written or oral discussions. (NASA supplements paragraph (c)).

(c)(2)(A) The contracting officer shall identify, and give offerors a reasonable opportunity to address, all weaknesses that have an adverse impact on the evaluation. Weaknesses are defined as deficiencies (see FAR 15.601) and other proposal inadequacies. Weaknesses may include all proposal areas that are inadequate for evaluation, contain contradictory statements, or strain credibility. However, minor irregularities, informalities, or apparent clerical mistakes are not considered weaknesses. They may be identified to offerors through the clarification technique defined in FAR 15.601, rather than discussions as contemplated in this section.

(B) The contracting officer shall advise an offeror if, during written or oral discussions, an offeror introduces a new weakness. The offeror can be advised during the course of the discussions or as part of the request for BAFO.

(C) The contracting officer shall identify any cost/price elements that do not appear to be justified and encourage offerors to submit their most favorable and realistic cost/price proposals, but shall not discuss, disclose, or compare cost/price elements of any other offeror. The contracting officer should question inadequate, conflicting, unrealistic or unsupported cost information; differences between the offeror's proposal and most probable cost assessments; cost realism concerns; differences between audit findings and

proposed costs; proposed rates that are too high/low; and labor mixes that do not appear responsive to the requirements. No agreement on cost/price elements or a ''bottom line'' is necessary.

(3)(A) The contracting officer shall discuss contract terms and conditions so that a ''model'' contract can be sent to each offeror with the request for BAFO. Any proposed technical performance capabilities above those specified in the RFP that have value to the Government and are considered proposal strengths should be discussed with the offeror and proposed for inclusion in that offeror's ''model'' contract. These items are not to be discussed with, or proposed to, other offerors. If the offeror declines to include these strengths in its ''model'' contract, the Government evaluators should reconsider their characterization as strengths.

(B) In no case shall the contracting officer relax or amend RFP requirements for any offeror, without amending the RFP and permitting the other offerors an opportunity to propose against the relaxed requirements.

1815.611 Best and Final Offers. (NASA supplements paragraphs (b), (c) and (d))

(b) The request for BAFOs shall also:

(i) Identify any remaining weaknesses;

(ii) Instruct offerors to incorporate all changes to their offers resulting from discussions, and require clear traceability from initial proposals;

(iii) Require offerors to complete and execute the ''model'' contract, which includes any special provisions or performance capabilities the offeror proposed above those specified in the RFP;

(iv) Caution offerors against unsubstantiated changes to their proposals; and

(v) Establish a page limit for BAFOs.

(c) (i) Approval of the Associate Administrator for Procurement (Code HS) is required to reopen discussions for acquisitions of $50 million more.

(ii) Approval of the procurement officer is required for all other acquisitions.

(d) (i) Proposals are rescored based on BAFO evaluations. Scoring changes between initial and BAFO proposals shall be clearly traceable.

(ii) All significant evaluation findings shall be fully documented and considered in the source selection decision. A clear and logical audit trail shall be maintained for the rationale for ratings and scores, including a detailed account of the decisions leading to the selection. Selection is made on the basis of the evaluation criteria established in the RFP.

(iii) Prior to award, the SSA shall sign a source selection statement that clearly and succinctly justifies the selection. Source selection statements must describe: the acquisition; the SEB evaluation procedures; the substance of the Mission Suitability evaluation; and the evaluation of the Cost/Price and Relevant Experience and Past Performance factors. The Statement also addresses unacceptable proposals, the competitive range determination, late proposals, or any other considerations pertinent to the decision. The statement shall not reveal any confidential business information. Except for certain major system acquisition competitions (see 1815.1004–70), source selection statements shall be releasable to competing offerors and the general public upon request. The statement shall be available to the Debriefing Official to use in debriefing unsuccessful offerors and shall be provided to debriefed offerors upon request.

(iv) Once the selection decision is made, the contacting officer shall, without post-selection negotiations, award the contract.

1815.612–70 NASA formal source selection

(a) The source evaluation board (SEB) procedures shall be used for those acquisitions identified in 1815.602(a)(i)(A).

(b) *General.* The SEB assists the SSA in decision making by providing expert analyses of the offerors' proposals in relation to the evaluation factors, subfactors, and elements contained in the solicitation. The SEB will prepare and present its findings to the SSA, avoiding trade-off judgments among either the individual offerors or among the evaluation factors. The SEB will not make recommendations for selection to the SSA.

(c) *Designation.* (1) The SEB shall be comprised of competent individuals fully qualified to identify the strengths, weaknesses, and risks associated with proposals submitted in response to the solicitation. The SEB shall be appointed as early as possible in the acquisition process, but not later than acquisition plan approval.

(2) While SEB participants are normally drawn from the cognizant installation, personnel from other NASA installations or other Government agencies may participate. When it is necessary to disclose the proposal (in whole or in part) outside the Government, approval shall be obtained in accordance with NFS 1815.413–2.

(3) When Headquarters retains SSA authority, the Headquarters Office of Procurement (Code HS) must concur on the SEB appointments. Qualifications of voting members, including functional title, grade level, and related SEB experience, shall be provided.

(d) *Organization.* (1) The organization of an SEB is tailored to the requirements of the particular acquisition. This can range from the simplest situation, where the SEB conducts the evaluation and fact-finding without the use of committees or panels/consultants (as described in 1815.612–70(d) (4) and (5)), to a highly complex situation involving a major acquisition where two or more committees are formed and these, in turn, are assisted by special panels or consultants in particular areas. The number of committees or panels/consultants shall be kept to a minimum.

(2) The SEB Chairperson is the principal operating executive of the SEB. The Chairperson is expected to manage the team efficiently without compromising the validity of the findings provided to the SSA as the basis for a sound selection decision.

(3) The SEB Recorder functions as the principal administrative assistant to the SEB Chairperson and is principally responsible for logistical support and record-keeping of SEB activities.

(4) An SEB committee functions as a fact-finding arm of the SEB, usually in a broad grouping of related disciplines (e.g., technical or management). The committee evaluates in detail each proposal, or portion thereof, assigned by the SEB in accordance with the approved evaluation factors, subfactors, and elements, and summarizes its evaluation in a written report to the SEB. The committee will also respond to requirements assigned by the SEB, including further justification or reconsideration of its findings. Committee chairpersons shall manage the administrative and procedural matters of their committees.

(5) An SEB panel or consultant functions as a fact-finding arm of the committee in a specialized area of the committee's responsibilities. Panels are established or consultants named when a particular area requires deeper analysis than the committee can provide.

(6) The total of all such evaluators (committees, panels, consultants, etc. excluding SEB voting members and ex officio members) shall be limited to a maximum of 20 people, unless approved in writing by the procurement officer.

(e) *Voting members.* (1) Voting members of the SEB shall include people who will have key assignments on the project to which the acquisition is directed. However, it is important that

this should be tempered to ensure objectivity and to avoid an improper balance. It may even be appropriate to designate a management official from outside the project as SEB Chairperson.

(2) Non-government personnel shall not serve as voting members of a NASA SEB.

(3) The SEB shall review the findings of committees, panels or consultants and use its own collective judgment to develop the SEB evaluation findings reported to the SSA. All voting members of the SEB shall have equal status as rating officials.

(4) SEB membership shall be limited to a maximum of 7 voting individuals. Wherever feasible, an assignment to SEB membership as a voting member shall be on a full-time basis. When not feasible, SEB membership shall take precedence over other duties.

(5) The following people shall be voting members of all SEBs:

(i) Chairperson.

(ii) A senior, key technical representative for the project.

(iii) An experience procurement representative.

(iv) A senior Safety & Mission Assurance (S&MA) representative, as appropriate.

(v) Committee chairpersons (except where this imposes an undue workload).

(f) *Ex officio members.* (1) The number of nonvoting ex officio (advisory) members shall be kept as small as possible. Ex officio members should be selected for the experience and expertise they can provide to the SEB. Since their advisory role may require access to highly sensitive SEB material and findings, ex officio membership for persons other than those identified in paragraph 1815.612–70(f)(3) is discouraged.

(2) Nonvoting ex officio members may state their views and contribute to the discussions in SEB deliberations, but they may not participate in the actual rating process. However, the SEB recorder should be present during rating sessions.

(3) For field installation selections, the following shall be nonvoting ex officio members on all SEBs:

(i) Chairpersons of SEB committees, unless designated as voting members.

(ii) The procurement officer of the installation, unless designated a voting member.

(iii) The contracting officer responsible for the acquisition, unless designated a voting member.

(iv) The Chief Counsel and/or designee of the installation.

(v) The installation small business specialist.

(vi) The SEB recorder.

(g) *Evaluation plan.* (1) The SEB evaluation plan consists of general and specific evaluation guidelines (and special standards of responsibility, where applicable) established to assess each offeror's proposal against the RFP evaluation factors, subfactors, and elements. The evaluation guidelines are designed to focus the evaluators' assessment. They are not weighted and are not listed in the RFP. However, the substance of the guidelines may be included in a narrative description of the subfactors and elements. In addition, the plan includes the system used in conducting the evaluation and scoring of each offeror's proposal.

(2) The evaluation plan shall be approved by the SEB (and other personnel designated in accordance with installation procedures) before the formal RFP is issued.

(h) *Evaluation.* (1) If committees are used, the SEB Chairperson shall send them the proposals or portions thereof to be evaluated, along with instructions regarding the expected function of each committee, and all data considered necessary or helpful.

(2) While oral reports may be given to the SEB, each committee shall submit a written report which should include the following:

(i) Copies of individual worksheets and supporting comments to the lowest level evaluated;

(ii) An evaluation sheet summarized for the committee as a whole; and

(iii) A statement for each proposal describing any strengths or weaknesses which significantly affected the evaluation and stating any reservations or concerns, together with supporting rationale, which the committee or any of its members want to bring to the attention of the SEB.

(3) Clear traceability must exist at all levels of the SEB process. All reports submitted by committees or panels will be retained as part of the SEB records.

(4) Each voting SEB member shall thoroughly review each proposal and any committee reports and findings. The SEB shall rate or score the proposals for each evaluation factor and subfactor according to its own collective judgment, consistent with the approved evaluation plan. SEB minutes shall reflect this evaluation process.

(i) *SEB presentation.* (1) The SEB Chairperson shall brief the SSA on the results of the SEB deliberations to permit an informed and objective selection of the best source(s) for the particular acquisition.

(2) The presentation shall focus on the major strengths and weaknesses found in the proposals, the probable cost of each proposal, and any significant issues and problems identified by the SEB. This presentation must explain any applicable special standards of responsibility; evaluation factors, subfactors, and elements; the major strengths and weaknesses of the offerors; the Government cost estimate, if applicable; the offerors' proposed cost/price; the probable cost; the proposed fee arrangements; and the final adjectival ratings and scores to the subfactor level.

(3) Attendance at the presentation is restricted to people involved in the selection process or who have a valid need to know. The designated individuals attending the SEB presentation(s) shall:

(i) Ensure that the solicitation and evaluation processes complied with all applicable agency policies and that the presentation accurately conveys the SEB's activities and findings;

(ii) Not change the established evaluation factors, subfactors, elements, weights, or scoring systems; or the substance of the SEB's findings. They may, however, advise the SEB to rectify procedural omissions, irregularities or inconsistencies, substantiate its findings, or revise the presentation.

(4) The SEB recorder will coordinate the formal presentation including arranging the time and place of the presentation, assuring proper attendance, and distributing presentation material.

(5) For Headquarters selections, the Headquarters Office of Procurement (Code HS) will coordinate the presentation, including approval of attendees. When the Administrator is the SSA, a preliminary presentation should be made to the Field Installation Director and to the Official-in-Charge of the cognizant Headquarters Program Office.

(j) *Recommended SEB presentation format.* (1) *Identification of acquisition.* Identifies the installation, the nature of the services or hardware to be procured, some quantitative measure including the Government cost estimate for the acquisition, and the planned contractual arrangement. Avoids detailed objectives of the acquisition.

(2) *Background.* Identifies any earlier phases of a phased acquisition or, as in the case of continuing support services, identifies the incumbent and any consolidations or proposed changes from the existing structure.

(3) *Evaluation factors, subfactors, and elements.* Explains any special standards of responsibility and the evaluation factors, subfactors, and elements. Lists the relative order of importance of the evaluation factors and

the numerical weights of the Mission Suitability subfactors. Presents the adjectival scoring system used in the Mission Suitability and Relevant Experience and Past Performance evaluations.

(4) *Sources.* Indicates the number of offerors solicited and the number of offerors expressing interest (e.g., attendance at a preproposal conference). Identifies the offerors submitting proposals, indicating any small businesses, small disadvantaged businesses, and women-owned businesses.

(5) *Summary of findings.* Lists the initial and final Mission Suitability ratings and scores, the offerors' proposed costs/prices, and any assessment of the probable costs. Introduces any clear discriminator, problem, or issue which could affect the selection. Addresses any competitive range determination.

(6) *Strengths and weaknesses of offerors.* Summarizes the SEB's findings, using the following guidelines:

(i) Present only the major strengths and weaknesses of individual offerors.

(ii) Directly relate the strengths and weaknesses to the evaluation factors, subfactors, and elements.

(iii) Indicate the significance of major strength and weaknesses.

(iv) Indicate the results and impact, if any, of written and/or oral discussions and BAFOs on ratings and scores.

(7) *Final mission suitability ratings and scores.* Summarizes the evaluation subfactors and elements, the maximum points achievable, and the scores of the offerors in the competitive range.

(8) *Final cost/price evaluation.* Summarizes proposed costs/prices and any probable costs associated with each offeror including proposed fee arrangements. Presents the data as accurately as possible, showing SEB adjustments to achieve comparability. Identifies the SEB's confidence in the probable costs of the individual offerors, noting the reasons for low or high confidence.

(9) *Relevant experience and past performance.* Reflects the summary conclusions, supported by specific case data, with particular emphasis on exemplary or inferior performance and its potential bearing on the instant acquisition.

(10) *Special interest.* Includes only information of special interest to the SSA that has not been discussed elsewhere, e.g., procedural errors or other matters that could have an effect on the selection decision.

(k) A source selection statement shall be prepared in accordance with 1815.611(d)(iii). For installation selections, the Field Installation Chief Counsel or designee will prepare the source selection statement. For Headquarters selections, the Office of General Counsel or designee will prepare the statement.

Subpart 1815.7—Make-or-Buy Programs

1815.704 Items and work included.

Make-or-buy programs should not include items or work efforts estimated to cost less than $500,000.

1815.706 Evaluation, negotiation, and agreement. (NASA supplements paragraph (b))

(b) The make-or-buy program review by the installation's small and disadvantaged business utilization specialist and the SBA representative should be concurrent with the contracting officer's review. When urgent circumstances preclude this or if the small and disadvantaged business specialist or SBA representative fails to respond on a timely basis, the contracting officer shall include an explanatory statement in the contract file and transmit copies to the specialist and the representative.

1815.708 Contract clause.

1815.708–70 NASA contract clause.

(a) The contracting officer shall insert the provision at 1852.215–78, Make-or-Buy Program Requirements; in solicitations requiring make-or-buy programs as provided in FAR 15.703. This provision shall be used in conjunction with the clause at FAR 52.215–21, Changes or Additions to Make-or-Buy Program. The contracting officer may add additional paragraphs identifying any other information required in order to evaluate the program.

(b) The contracting officer shall insert the clause at 1852.215–79, Price Adjustment for ''Make-or-Buy'' Changes, in contracts that include FAR 52.215–21 with its Alternate I or II. Insert in the appropriate columns the items that will be subject to a reduction in the contract value.

Subpart 1815.8—Price Negotiation

1815.804 Cost or pricing data and information other than cost or pricing data.

1815.804–1 Prohibition on obtaining cost or pricing data. (NASA supplements paragraph (b))

(b)(1) The adequate price competition exception is applicable to both fixed-price and cost-reimbursement type acquisitions. Contracting officers shall assume that all competitive acquisitions qualify for this exception. In such cases, information other than cost or pricing data may be requested to the extent necessary to ensure price reasonableness and assess cost realism.

(2)(iii) The contracting officer shall document the comparison of the item with the catalog or market priced commercial item, including the technical similarities and differences and the price justification methodology.

(5) Waivers of the requirement for submission of cost or pricing data shall be prepared in accordance with FAR 1.704. A copy of each waiver shall be sent to the Headquarters Office of Procurement (Code HC).

1815.804–170 Acquisitions with the Canadian Commercial Corporation (CCC).

NASA has waived the requirement for the submission of cost or pricing data when contracting with the CCC. This waiver applies through March 31, 1999. The CCC will provide assurance of the fairness and reasonableness of the proposed prices, and will also provide for follow-up audit activity to ensure that excess profits are found and refunded to NASA. However, contracting officers shall ensure that the appropriate level of information other than cost or pricing data is submitted to permit any required Government cost/price analysis.

1815.804–2 Requiring cost or pricing data. (NASA supplements paragraph (b))

(b)(2) If a certificate of current cost or pricing data is made applicable as of a date other than the date of price agreement, the agreed date should generally be within two weeks of the date of price agreement.

1815.805–5 Field pricing support. (NASA supplements paragraph (a))

(a)(1)(A) The threshold for obtaining a field pricing report for cost reimbursement contracts is $1,000,000.

(B) A field pricing report consists of a technical report and an audit report by the cognizant contract audit activity. Contracting officers should request a technical report from the ACO only if NASA resources are not available.

(C) When the required participation of the ACO or auditor involves merely a verification of information, contracting officers should obtain this verification from the cognizant office by telephone rather than formal request of field pricing support.

(D) When the threshold for requiring field pricing support is met and the cost proposal is for a product of a follow-on nature, contracting officers shall ensure that the following items, at a minimum are considered: actuals incurred under the previous contract, learning

experience, technical and production analysis, and subcontract proposal analysis. This information may be obtained through NASA resources or the cognizant DCMC ACO or DCAA.

1816.807 Prenegotiation objectives. (NASA supplements paragraph (b))

(b)(i) Before conducting negotiations requiring installation or Headquarters review, contracting officers or their representatives shall prepare a prenegotiation position memorandum setting forth the technical, business, contractual, pricing, and other aspects to be negotiated.

(ii) A prenegotiation position memorandum is not required for contracts awarded under competitive negotiated procedures.

1815.807–70 Content of the prenegotiation position memorandum.

The prenegotiation position memorandum (PPM) should fully explain the contractor and Government positions. Since the PPM will ultimately become the basis for negotiation, it should be structured to track to the price negotiation memorandum (see FAR 15.808 and 1815.808). In addition to the information described in FAR 15.807 and, as appropriate, 15.808(a), the PPM should address the following subjects, as applicable, in the order presented:

(a) *Introduction.* Include a description of the acquisition and a history of prior acquisitions for the same or similar items. Address the extent of competition and its results. Identify the contractor and place of performance (if not evident from the description of the acquisition). Document compliance with law, regulations and policy, including JOFOC, synopsis, method of contracting D&F, EEO compliance, and current status of contractor systems (see FAR 15.808(a)(4)). In addition, the negotiation schedule should be addressed and the Government negotiation team members identified by name and position.

(b) *Type of contract contemplated.* Explain the type of contract contemplated and the reasons for its suitability.

(c) *Special features and requirements.* In this area, discuss any special features (and related cost impact) of the acquisition, including such items as—

(1) Letter contract or precontract costs authorized and incurred;

(2) Results of preaward survey;

(3) Contract option requirements;

(4) Government property to be furnished;

(5) Contractor/Government investment in facilities and equipment (and any modernization to be provided by the contractor/Government); and

(6) Any deviation, special clauses, or unusual conditions anticipated, for example, unusual financing, warranties, EPA clauses and when approvals were obtained, if required.

(d) *Cost analysis.* For the basic requirement, and any option, include—

(1) A parallel tabulation, by element of cost and profit/fee, of the contractor's proposal and the Government's negotiation objective. The negotiation objective represents the fair and reasonable price the Government is willing to pay for the supplies/services. For each element of cost, compare the contractor's proposal and the Government position, explain the differences and how the Government position was developed, including the estimating assumptions and projection techniques employed, and how the positions differ in approach. Include a discussion of excessive wages found (if applicable) and their planned resolution. Explain how historical costs, including costs incurred under a letter contract (if applicable), were used in developing the negotiation objective;

(2) Significant differences between the field pricing report (including any audit reports) and the negotiation objectives and/or contractor's proposal shall be highlighted and explained. For each proposed subcontract meeting the requirement of FAR 15.806–2(a), there shall be a discussion of the price and, when appropriate, cost analyses performed by the contracting officer, including the negotiation objective for each such subcontract. The discussion of each major subcontract shall include the type of subcontract, the degree of competition achieved by the prime contractor, the price and, when appropriate, cost analyses performed on the subcontractor's proposal by the prime contractor, any unusual or special pricing or finance arrangements, and the current status of subcontract negotiations.

(3) The rationale for the Government's profit/fee objectives and, if appropriate, a completed copy of the NASA Form 634, Structured Approach—Profit/Fee Objective, and DD Form 1861, Contract Facilities Capital Cost of Money, should be included. For incentive and award fee contracts, describe the planned arrangement in terms of share lines, ceilings, cost risk, and so forth, as applicable.

(e) *Negotiation approval sought.* The PPM represents the Government's realistic assessment of the fair and reasonable price for the supplies and services to be acquired. If negotiations subsequently demonstrate that a higher dollar amount (or significant term or condition) is reasonable, the contracting officer shall document the rationale for such a change and request approval to amend the PPM from the original approval authority.

1815.807–71 Installation reviews.

Each contracting activity shall establish a formal system for the review of prenegotiation position memoranda. The scope of coverage, exact procedures to be followed, levels of management review, and contract file documentation requirements should be directly related to the dollar value and complexity of the acquisition. The primary purpose of these reviews is to ensure that the negotiator, or negotiating team, is thoroughly prepared to enter into negotiations with a well-conceived, realistic, and fair plan.

1815.807–72 Headquarters reviews.

(a) When a prenegotiation position has been selected for Headquarters review and approval, the contracting activity shall submit to the Office of Procurement (Code HS) one copy each of the prenegotiation position memorandum, the contractor's proposal, the Government technical evaluation, and all pricing reports (including any audit reports).

(b) The required information described in paragraph (a) of this section shall be furnished to Headquarters as soon as practicable and sufficiently in advance of the planned commencement of negotiations to allow a reasonable period of time for Headquarters review. Electronic submittal is acceptable.

1815.808 Price negotiation memorandum. (NASA supplements paragraphs (a) and (b))

(a)(i) The price negotiation memorandum (PNM) serves as a detailed summary of: the technical, business, contractual, pricing (including price reasonableness), and other elements of the contract negotiated; and the methodology and rationale used in arriving at the final negotiated agreement.

(ii) A PNM is not required for a contract awarded under competitive negotiated procedures. However, the information required by FAR 15.808 shall be reflected in the evaluation and selection documentation to the extent applicable.

(b) When the PNM is a ''stand-alone'' document, it shall contain the information required by the FAR and NFS for both PPMs and PNMs. However, when a PPM has been prepared under 1815.807, the subsequent PNM need only provide any

information required by FAR 15.808 that was not provided in the PPM, as well as any changes in the status of factors affecting cost elements (e.g., use of different rates, hours, subcontractors; wage rate determinations; or the current status of the contractor's systems).

Subpart 1815.9—Profit

1815.902 Policy. (NASA supplements paragraph (a))

(a)(1) The NASA structured approach for determining profit or fee objectives, described in 1815.970, shall be used to determine profit or fee objectives for conducting negotiations in those acquisitions that require cost analysis, except as indicated in paragraph (a)(2) of this section.

(a)(2) The use of the NASA structured approach for profit or fee is not required for:

(A) Architect-engineer contracts;

(B) Management contracts for operation and/or maintenance of Government facilities;

(C) Construction contracts;

(D) Contracts primarily requiring delivery of material supplied by subcontractors;

(E) Termination settlements;

(F) Cost-plus-award-fee contracts (however, contracting officers may find it advantageous to perform a structured profit/fee analysis as an aid in arriving at an appropriate fee arrangement); and

(G) Contracts having unusual pricing situations when the procurement officer determines in writing that the structured approach is unsuitable and the exemption is:

(*1*) Justified in writing, and

(*2*) Authorized by the procurement officer.

1815.903 Contracting officer responsibilities. (NASA supplements paragraph (d))

(d)(1)(ii) In architect-engineer contracts, the price or estimated cost and fee for services other than the production and delivery of designs, plans, drawings, and specifications, are not subject to the 6 percent limitation set forth in FAR 15.903(d)(1).

1815.970 NASA structured approach for profit or fee objective.

1815.970–1 General.

(a) The NASA structured approach for determining profit or fee objectives is a system of assigning weights to cost elements and other factors to calculate the objective. Contracting officers shall use NASA Form 634 to develop the profit or fee objective and shall use the weight ranges listed after each category and factor on the form after considering the factors in 1815.970–2 through 1815.970–4. The rationale supporting the assigned weights shall be documented in the PPM in accordance with 1815.807–70(d)(3).

(b)(1) The structured approach was designed for determining profit or fee objectives for commercial organizations. However, the structured approach shall be used as a basis for arriving at fee objectives for nonprofit organizations (FAR subpart 31.7), excluding educational institutions (FAR subpart 31.3), in accordance with paragraph (b)(2) of this section. (It is NASA policy not to pay profit or fee on contracts with educational institutions.)

(2) For contracts with nonprofit organizations under which profits or fees are involved, an adjustment of up to 3 percent shall be subtracted from the total profit/fee objective. In developing this adjustment, it will be necessary to consider the following factors:

(i) Tax position benefits;

(ii) Granting of financing through letters of credit;

(iii) Facility requirements of the nonprofit organization; and

(iv) Other pertinent factors that may work to either the advantage or disadvantage of the contractor in its position as a nonprofit organization.

1815.970–2 Contractor effort.

(a) This factor takes into account what resources are necessary and what the contractor must do to meet the contract performance requirements. The suggested cost categories under this factor are for reference purposes only. The format of individual proposals will vary, but these broad categories provide a sample structure for the evaluation of all categories of cost. Elements of cost shall be separately listed under the appropriate category and assigned a weight from the category range.

(b) Regardless of the categories of cost defined for a specific acquisition, neither the cost of facilities nor the amount calculated for the cost of money for facilities capital shall be included as part of the cost base in column 1.(a) in the computation of profit or fee.

(c) Evaluation of this factor requires analyzing the cost content of the proposed contract as follows:

(1) *Material acquisition (subcontracted items, purchased parts, and other material.).* (i) Consider the managerial and technical efforts necessary for the prime contractor to select subcontractors and administer subcontracts, including efforts to introduce and maintain competition. These evaluations shall be performed for purchases of raw materials or basic commodities; purchases of processed material, including all types of components of standard or near-standard characteristics; and purchases of pieces, assemblies, subassemblies, special tooling, and other products special to the end item. In performing the evaluation, also consider whether the contractor's purchasing program makes a substantial contribution to the performance of a contract through the use of subcontracting programs involving many sources, new complex components and instrumentation, incomplete specifications, and close surveillance by the prime contractor.

(ii) Recognized costs proposed as direct material costs, such as scrap charges, shall be treated as material for profit/fee evaluation. If intracompany transfers are accepted at price in accordance with FAR 31.205–26(e), they shall be evaluated as a single element under the material acquisition category. For other intracompany transfers, the constituent elements of cost shall be identified and weighted under the appropriate cost category, i.e., material, labor, and overhead.

(2) *Direct labor (engineering, service, manufacturing, and other labor).* (i) Analysis of the various items of cost should include evaluation of the comparative quality and level of the engineering talents, service contract labor, manufacturing skills, and experience to be employed. In evaluating engineering labor for the purpose of assigning profit/fee weights, consideration should be given to the amount of notable scientific talent or unusual or scarce engineering talent needed, in contrast to journeyman engineering effort or supporting personnel.

(ii) Evaluate service contract labor in a like manner by assigning higher weights to engineering, professional, or highly technical skills and lower weights to semiprofessional or other skills required for contract performance.

(iii) Similarly, the variety of engineering, manufacturing and other types of labor skills required and the contractor's manpower resources for meeting these requirements should be considered. For purposes of evaluation, subtypes of labor (for example, quality control, and receiving and inspection) proposed separately from engineering, service, or manufacturing labor should be included in the most appropriate labor type. However, the same evaluation considerations as outlined above will be applied.

(3) *Overhead and general management (G&A).* (i) Analysis of overhead and G&A includes the evaluation of the makeup of these expenses, how much they contribute to

contract performance, and the degree of substantiation provided for rates proposed in future years.

(ii) Contracting officers should also consider the historical accuracy of the contractor's proposed overheads as well as the ability to control overhead pool expenses.

(iii) The contracting officer, in an evaluation of the overhead rate of a contractor using a single indirect cost rate, should break out the applicable sections of the composite rate which could be classified as engineering overhead, manufacturing overhead, other overhead pools, and G&A expenses, and apply the appropriate weight.

(4) *Other costs.* Include all other direct costs associated with contractor performance under this item, for example, travel and relocation, direct support, and consultants. Analysis of these items of cost should include their nature and how much they contribute to contract performance.

1815.970–3 Other factors.

(a) *Cost risk.* The degree of risk assumed by the contractor should influence the amount of profit or fee a contractor is entitled to anticipate. For example, if a portion of the risk has been shifted to the Government through cost-reimbursement or price redetermination provisions, unusual contingency provisions, or other risk reducing measures, the amount of profit or fee should be less than for arrangements under which the contractor assumes all the risk. This factor is one of the most important in arriving at prenegotiation profit/fee objectives.

(1) Other risks on the part of the contractor, such as loss of reputation, losing a commercial market, or losing potential profit/fee in other fields, shall not be considered in this factor. Similarly, any risk on the part of the contracting office, such as the risk of not acquiring an effective space vehicle, is not within the scope of this factor.

(2) The degree of cost responsibility assumed by the contractor is related to the share of total contract cost risk assumed by the contractor through the selection of contract type. The weight for risk by contract type would usually fall within the 0–to–3 percent range for cost-reimbursement contracts and 3–to–7 percent range for fixed-price contracts.

(i) Within the ranges set forth in paragraph (a)(2) of this section, a cost-plus-fixed-fee contract normally would not justify a reward for risk in excess of 0 percent, unless the contract contains cost risk features such as ceilings on overheads, etc. In such cases, up to 0.5 percent may be justified. Cost-plus-incentive-fee contracts fill the remaining portion of the range, with weightings directly related to such factors as confidence in target cost, share ratio of fees, etc.

(ii) The range for fixed-price type contracts is wide enough to accommodate the various types of fixed-price arrangements. Weighting should be indicative of the price risk assumed and the end item required, with only firm-fixed-price contracts with requirements for prototypes or hardware reaching the top end of the range.

(3) The cost risk arising from contract type is not the only form of cost risk to consider.

(i) The contractor's subcontracting program may have a significant impact on the contractor's acceptance of risk under a particular contract type. This consideration should be a part of the contracting officer's overall evaluation in selecting a weight to apply for cost risk. It may be determined, for instance, that the prime contractor has effectively transferred real cost risk to a subcontractor, and the contract cost risk weight may, as a result, be below the range that would otherwise apply for the contract type proposed. The contract cost risk weight should not be lowered, however, merely on the basis that a substantial portion of the contract costs represents subcontracts unless those subcontract costs represent a substantial transfer of the contractor's risk.

(ii) In making a contract cost risk evaluation in an acquisition that involves definitization of a letter contract, unpriced change orders, or unpriced orders under BOAs, consideration should be given to the effect on total contract cost risk as a result of having partial performance before definitization. Under some circumstances it may be reasoned that the total amount of cost risk has been effectively reduced. Under other circumstances it may be apparent that the contractor's cost risk is substantially unchanged. To be equitable, determination of a profit/fee weight for application to the total of all recognized costs, both incurred and yet to be expended, must be made with consideration of all attendant circumstances and should not be based solely on the portion of costs incurred, or percentage of work completed, before definitization.

(b) *Investment.* NASA encourages its contractors to perform their contracts with a minimum of financial, facilities, or other assistance from the Government. As such, it is the purpose of this factor to encourage the contractor to acquire and use its own resources to the maximum extent possible. Evaluation of this factor should include an analysis of the contractor's facilities and the frequency of payments.

(1) To evaluate how facilities contribute to the profit/fee objective requires knowledge of the level of facilities utilization needed for contract performance, the source and financing of the required facilities, and the overall cost effectiveness of the facilities offered. Contractors furnishing their own facilities that significantly contribute to lower total contract costs should be provided additional profit/fee. On the other hand, contractors that rely on the Government to provide or finance needed facilities should receive a correspondingly lower profit/fee. Cases between the above examples should be evaluated on their merits, with either a positive or negative adjustment, as appropriate, in the profit/fee objective. However, where a highly facilitized contractor is to perform a contract that does not benefit from this facilitization, or when a contractor's use of its facilities has a minimum cost impact on the contract, profit/fee need not be adjusted.

(2) In analyzing payments, consider the frequency of payments by the Government to the contractor and unusual payments. The key to this weighting is proper consideration of the impact the contract will have on the contractor's cash flow. Generally, negative consideration should be given for payments more frequent than monthly, with maximum reduction being given as the contractor's working capital approaches zero. Positive consideration should be given for payments less frequent than monthly.

(c) *Performance.* The contractor's past and present performance should be evaluated in such area as product quality, meeting performance schedules, efficiency in cost control (including the need for and reasonableness of costs incurred), accuracy and reliability of previous cost estimates, degree of cooperation by the contractor (both business and technical), timely processing of changes and compliance with other contractual provisions.

(d) *Subcontract program management.* Subcontract program management includes evaluation of the contractor's commitment to its competition program and its past and present performance in competition in subcontracting. If a contractor has consistently achieved excellent results in these areas in comparison with other contractors in similar circumstances, such performance merits a proportionately greater opportunity for profit or fee. Conversely, a poor record

in this regard should result in a lower profit or fee.

(e) *Federal socioeconomic programs.* In addition to rewarding contractors for unusual initiative in supporting Government socioeconomic programs, failure or unwillingness on the part of the contractor to support these programs should be viewed as evidence of poor performance for the purpose of establishing this profit/fee objective factor.

(f) *Special situations.* (1) Occasionally, unusual contract pricing arrangements are made with the contractor under which it agrees to accept a lower profit or fee for changes or modifications within a prescribed dollar value. In such circumstances, the contractor should receive favorable consideration in developing the profit/fee objective.

(2) This factor need not be limited to situations that increase profit/fee levels. A negative consideration may be appropriate when the contractor is expected to obtain spin-off benefits as a direct result of the contract, for example, products with commercial application.

1815.970–4 Facilities capital cost of money.

(a) When facilities capital cost of money is included as an item of cost in the contractor's proposal, it shall not be included in the cost base for calculating profit/fee. In addition, a reduction in the profit/fee objective shall be made in the amount equal to the facilities capital cost of money allowed in accordance with FAR 31.205–10(a)(2).

(b) CAS 417, cost of money as an element of the cost of capital assets under construction, should not appear in contract proposals. These costs are included in the initial value of a facility for purposes of calculating depreciation under CAS 414.

1815.971 Payment of profit or fee under letter contracts.

NASA's policy is to pay profit or fee only on definitized contracts.

Subpart 1815.10—Preaward, Award, and Postaward Notifications, Protests, and Mistakes

1815.1003 Notification to successful offeror.

The reference to notice of award in FAR 15.1003 on negotiated acquisitions is a generic one. It relates only to the formal establishment of a contractual document obligating both the Government and the offeror. The notice is effected by the transmittal of a fully approved and executed definitive contract document, such as the award portion of SF 33, SF 26, SF 1449, or SF 1447, or a letter contract when a definitized contract instrument is not available but the urgency of the requirement necessitates immediate performance. In this latter instance, the procedures in 1816.603 for approval and issuance of letter contracts shall be followed.

1815.1004–70 Debriefing of offerors—Major System acquisitions.

(a) When an acquisition is conducted in accordance with the Major System acquisition procedures in part 1834 and multiple offerors are selected, the debriefing will be limited in such a manner that it does not prematurely disclose innovative concepts, designs, and approaches of the successful offerors that would result in a transfusion of ideas.

(b) When Phase B awards are made for alternative system design concepts, the source selection statements shall not be released to competing offerors or the general public until the release of the source selection statement for Phase C/D without the approval of the Associate Administrator for Procurement (Code HS).

Subpart 1815.70—Ombudsman

1815.7001 NASA Ombudsman Program.

NASA's implementation of an ombudsman program is in NPG 5101.33, Procurement Guidance.

1815.7002 Synopses of solicitations and contracts.

In all synopses announcing competitive acquisitions, the contracting officer shall indicate that the clause at 1852.215–84, Ombudsman, is applicable. This may be accomplished by referencing the clause number and identifying the installation Ombudsman.

1815.7003 Contract clause.

The contracting officer shall insert a clause substantially the same as the one at 1852.215–84, Ombudsman, in all solicitations (including draft solicitations) and contracts.

3. Part 1816 is revised to read as follows:

PART 1816—TYPES OF CONTRACTS

Subpart 1816.2—Fixed-Price Contracts

1816.202 Firm-fixed-price contracts.
1816.202–70 NASA contract clause.
1816.203 Fixed-price contracts with economic price adjustment.
1816.203–4 Contract clauses.

Subpart 1816.3—Cost-Reimbursement Contracts

1816.303–70 Cost-sharing contracts.
1816.306 cost-plus-fixed-fee contracts.
1816.307 Contract clauses.
1816.307–70 NASA contract clauses.

Subpart 1816.4—Incentive Contracts

1816.402 Application of predetermined, formula-type incentives.
1816.402–2 Technical performance incentives.
1816.402–270 NASA technical performance incentives.
1816.404 Cost-reimbursement incentive contracts.
1816.404–2 Cost-plus-award-fee (CPAF) contracts.
1816.404–270 CPAF contracts.
1816.404–271 Base fee.
1816.404–272 Award fee evaluation periods.
1816.404–273 Award fee evaluations.
1816.404–274 Award fee evaluation factors.
1816.404–275 Award fee evaluation scoring.
1816.405 Contract clauses.
1816.405–70 NASA contract clauses.

Subpart 1816.5—Indefinite-Delivery Contracts

1816.504 Indefinite quantity contracts
1816.505 Ordering.
1816.505–70 Task ordering.
1816.506–70 NASA contract clause.

Subpart 1816.6—Time-and-Materials, Labor-Hour, and Letter Contracts

1816.603 Letter contracts.
1816.603–370 Approvals.

Authority: 42 U.S.C. 2473(c)(1)

Subpart 1816.2—Fixed-Price Contracts

1816.202 Firm-fixed-price contracts.

1816.202–70 NASA contract clause.

The contracting officer shall insert the clause at 1852.216–78, Firm-Fixed-Price, in firm-fixed-price solicitations and contracts. Insert the appropriate amount in the resulting contract.

1816.203 Fixed-price contracts with economic price adjustments.

1816.203–4 Contract clauses. (NASA supplements paragraphs (a) and (d))

(a) In addition to the approval requirements in the prescriptions at FAR 52.216–2 through 42.216–4, the contracting officer shall coordinate with the installation's Deputy Chief Financial Officer (Finance) before exceeding the ten-percent limit in paragraph (c)(1) of the clauses at FAR 52.216–2 through 52.216–4.

(d)(2) Contracting officers shall contact the Office of Procurement, Code HC, for specific guidance on preparing clauses using cost indexes. Such clauses require advance approval by the Associate Administrator for Procurement. Requests for approval

shall be submitted to the Headquarters Office of Procurement (Code HS).

Subpart 1816.3—Cost-Reimbursement Contracts

1816.303–70 Cost-sharing contracts.

(a) *Cost-sharing with for-profit organizations.* (1) Cost sharing by for-profit organizations is mandatory in any contract for basic or applied research resulting from an unsolicited proposal, and may be accepted in any other contract when offered by the proposing organization. The requirement for cost-sharing may be waived when the contracting officer determines in writing that the contractor has no commercial, production, education, or service activities that would benefit from the results of the research, and the contractor has no means of recovering its shared costs on such projects.

(2) The contractor's cost-sharing may be any percentage of the project cost. In determining the amount of cost-sharing, the contracting officer shall consider the relative benefits to the contractor and the Government. Factors that should be considered include—

(i) The potential for the contractor to recover its contribution from non-Federal sources;

(ii) The extent to which the particular area of research requires special stimulus in the national interest; and

(iii) The extent to which the research effort or result is likely to enhance the contractor's capability, expertise, or competitive advantage.

(b) *Cost-sharing with not-for-profit organizations.* (1) Costs to perform research stemming from an unsolicited proposal by universities and other educational or not-for-profit institutions are usually fully reimbursed. When the contracting officer determines that there is a potential for significant benefit to the institution cost-sharing will be considered.

(2) The contracting officer will normally limit the institution's share to no more than 10 percent of the project's cost.

(c) *Implementation.* Cost-sharing shall be stated as a minimum percentage of the total allowable costs of the project. The contractor's contributed costs may not be charged to the Government under any other contract or grant, including allocation to other contracts and grants as part of an independent research and development program.

1816.306 Cost-plus-fixed-fee contracts. (NASA supplements paragraph (d))

(d) *Completion and term forms.* (4) Term form contracts are incompatible with performance based contracting (PBC) and should not be used with PBC requirements.

1816.307 Contract clauses. (NASA supplements paragraphs (a), (b), (d) and (g))

(a) In paragraph (h)(2)(ii)(B) of the Allowable Cost and Payment clause at FAR 52.216.7, the period of years may be increased to correspond with any statutory period of limitation applicable to claims of third parties against the contractor; provided, that a corresponding increase is made in the period for retention of records required in paragraph (f) of the clause at FAR 52.215–2, Adult and Records—Negotiation.

(b) In solicitations and contracts containing the clause at FAR 52.216–8, Fixed Fee, the Schedule shall include appropriate terms, if any, for provisional billing against fee.

(d) In solicitations and contracts containing the clause at FAR 52.216–10, Incentive Fee, the Schedule shall include appropriate terms, if any, for provisional billing against fee.

(g) In paragraph (g)(2)(ii) of the Allowable Cost and Payment—Facilities clause at FAR 52.216–13, the period of years may be increased to correspond with any statutory period of limitation applicable to claims of third parties against the contractor; provided, that a corresponding increase is made in the period for retention of records required in paragraph (f) of the clause at FAR 52.215–2, Adult and Records—Negotiation.

1816.307–70 NASA contract clauses.

(a) The contracting officer shall insert the clause at 1852.216–73, Estimated Cost and Cost Sharing, in each contract in which costs are shared by the contractor pursuant to 1816.303–70.

(b) The contracting officer shall insert the clause substantially as stated at 1852.216.74, Estimated Cost and Fixed Fee, in cost-plus-fixed-fee contracts.

(c) The contracting officer may insert the clause at 1852.216–75, Payment of Fixed Fee, in cost-plus-fixed-fee contracts. Modifications to the clause are authorized.

(d) The contracting officer shall insert the clause at 1852.216–81, Estimated Cost, in cost-no-fee contracts that are not cost sharing or facilities contracts.

(e) The contracting officer may insert a clause substantially as stated at 1852.216–87, Submission of Vouchers for Payment, in cost-reimbursement solicitations and contracts.

(f) When either FAR clause 52.216–7, Allowable Cost and Payment, or FAR clause 52.216–13, Allowable Cost and Payment—Facilities, is included in the contract, as prescribed at FAR 16.307 (a) and (g), the contracting officer should include the clause at 1852.216–89, Assignment and Release Forms.

Subpart 1816.4—Incentive Contracts

1816.402 Application of pre-determined, formula-type incentives.

1816.402–2 Technical performance incentives.

1816.402–270 NASA technical performance incentives.

(a) A performance incentive shall be included in all contracts where the primary deliverable(s) is (are) hardware and where total estimated cost and fee is greater than $25 million unless it is determined that the nature of the acquisition (for example, commercial off-the-shelf computers) would not effectively lend itself to a performance incentive. Any exception to this requirement shall be approved in writing by the Center Director. Performance incentives may be included in hardware contracts valued under $25 million at the discretion of the procurement officer. Performance incentives, which are objective and measure hardware performance after delivery and acceptance, are separate from other incentives, such as cost or delivery incentives.

(b) When a performance incentive is used, it shall be structured to be both positive and negative based on hardware performance after delivery and acceptance. In doing so, the contract shall establish a standard level of performance based on the salient hardware performance requirement. This standard performance level is normally the contract's minimum performance requirement. No incentive amount is earned at this standard performance level. Discrete units of measurement based on the same performance parameter shall be identified for performance both above and below the standard. Specific incentive amounts shall be associated with each performance level from maximum beneficial performance (maximum positive incentive) to minimal beneficial performance or total failure (maximum negative incentive). The relationship between any given incentive, both positive and negative, and its associated unit of measurement should reflect the value to the Government of tha level of hardware performance. The contractor should not be rewarded for above-standard performance levels that are of no benefit to the Government.

(c) The final calculation of the performance incentive shall be done when hardware performance, as defined

in the contract, ceases or when the maximum positive incentive is reached. When hardware performance ceases below the standard established in the contract, the Government shall calculate the amount due and the contractor shall pay the Government that amount. Once hardware performance exceeds the standard, the contractor may request payment of the incentive amount associated with a given level of performance, provided that such payments shall not be more frequent than monthly. When hardware performance ceases above the standard level of performance, or when the maximum positive incentive is reached, the Government shall calculate the final performance incentive earned and unpaid and promptly remit it to the contractor. The exclusion at FAR 16.405(e)(3) does not apply to decisions made as to the amount(s) of positive or negative incentive.

(d) When the deliverable hardware lends itself to multiple, meaningful measures of performance, multiple performance incentives may be established. When the contract requires the sequential delivery of several hardware items (e.g., multiple spacecraft), separate performance incentive structures may be established to parallel the sequential delivery and use of the deliverables.

(e) In determining the value of the maximum performance incentives available, the contracting officer shall follow the following rules.

(1) The sum of the maximum positive performance incentive and other fixed or earnable fees on the contract shall not exceed the limitations in FAR 15.903(c).

(2) For an award fee contract.

(i) The individual values of the maximum positive performance incentive and the total potential award fee (including any base fee) shall each be at least one-third of the total potential contract fee. The remaining one-third of the total potential contract fee may be divided between award fee and the maximum performance incentive at the discretion of the contracting officer.

(ii) The maximum negative performance incentive for research and development hardware (e.g., the first and second units) shall be equal in amount to the total *earned* award fee (including any base fee). The maximum negative performance incentives for production hardware (e.g., the third and all subsequent units of any hardware items) shall be equal in amount to the total *potential* award fee (including any base fee). Where one contract contains both cases described above, any base fee shall be allocated reasonably among the items.

(3) For cost reimbursement contracts other than award fee contracts, the maximum negative performance incentives shall not exceed the total earned fee under the contract.

1816.404 Cost-reimbursement incentive contracts.

1816.404–2 Cost-plus-award-fee (CPAF) contracts.

1816.404–270 CPAF contracts.

(a) For purposes of this subsection, ''performance based contracting'' means effort which can be contractually defined so that the results of the contractor's effort can be objectively measured in terms of technical and quality achievement, schedule progress or cost performance. ''Nonperformance based contracting'' means contractor effort that cannot be objectively measured but is evaluated based on subjective, qualitative assessments (e.g., controlling changes or interfacing with other agencies, contractors and international organizations).

(b)(1) Normally, award fee incentives are not used when contract requirements can be defined in sufficient detail to allow for performance based contracting. If incentives are considered necessary, objectively measured incentives as described in FAR 16.402 are preferred.

(2) Award fee incentives may be used as follows:

(i) As a CPAF contract where a cost reimbursement contract is appropriate and none of the requirements can be defined to permit performance based contracting;

(ii) As a CPAF line item for nonperformance based requirements in conjunction with a non-CPAF line item(s) for performance based requirements. In this instance, fees for the performance based and nonperformance based requirements shall be developed separately IAW FAR 15–9 and 1815.9; and

(iii) Under a performance based contract when it is determined to be necessary to motivate the contractor toward exceptional performance (see FAR 16.404–2(b)(ii)) and the increased level of performance justifies the additional administrative expense. When an award fee incentive is used in this instance, the basic contract type shall be other than CPAF (e.g., CPIF or FPIF). The potential award fee should not exceed 10 percent of the total contract fee or profit and shall not be used to incentivize cost performance.

(3) Award fee incentives shall not be used with a CPAF contract.

(c) Use of an award fee incentive shall be approved in writing by the procurement officer. The procurement officer's approval shall include a discussion of the other types of contracts considered and shall indicate why award fee incentive is the appropriate choice. Award fee incentives should be used on contracts with a total estimated cost and fee greater than $2 million per year. The procurement officer may authorize use of award fee for lower-valued acquisitions, but should do so only in exceptional situations, such as contract requirements having direct health or safety impacts, where the judgmental assessment of the quality of contractor performance is critical.

1816.404–271 Base fee.

(a) A base fee shall not be used on CPAF contracts for which the periodic award fee evaluations are final (1816.404–273(a)). In these circumstances, contractor performance during any award fee period is independent of and has no effect on subsequent performance periods or the final product/results at contract completion. For other contracts, such as those for hardware or software development, the procurement officer may authorize the use of a base fee not to exceed 3 percent. Base fee shall not be used when an award fee incentive is used in conjunction with a performance based contract structure, such as an incentive fee arrangement.

(b) When a base fee is authorized for use in a CPAF contract, it shall be paid only if the final award fee evaluation is ''satisfactory'' or better. (See 1816.404–273 and 1816.404–275) Pending final evaluation, base fee may be paid during the life of the contract at defined intervals on a provisional basis. If the final award fee evaluation is ''poor/unsatisfactory'', all provisional base fee payments shall be refunded to the Government.

1816.404–272 Award fee evaluation periods.

(a) Award fee evaluation periods should be at least 6 months in length. When appropriate, the procurement officer may authorize shorter evaluation periods after ensuring that the additional administrative costs associated with the shorter periods are offset by benefits accruing to the Government. Where practicable, such as developmental contracts with defined performance milestones (e.g., Preliminary Design Review, Critical Design Review, initial system test), establishing evaluation periods at the conclusion of the milestones rather than

calendar dates, or in combination with calendar dates should be considered. In no case shall an evaluation period be longer than 12 months.

(b) A portion of the total available award fee contract shall be allocated to each of the evaluation periods. This allocation may result in an equal or unequal distribution of fee among the periods. The contracting officer should consider the nature of each contract and the incentive effects of fee distribution in determining the appropriate allocation structure.

1816.404–273 Award fee evaluations.

(a) Award fee evaluations are either interim or final. On contracts where the contract deliverable is the performance of a service over any given time period, contractor performance is often definitively measurable within each evaluation period. In these cases, all evaluations are final, and the contractor keeps the fee earned in any period regardless of the evaluations of subsequent periods. Unearned award fee in any given period in a service contract is lost and shall not be carried forward, or ''rolled-over,'' into subsequent periods.

(b) On other contracts, such as those for end item deliverables where the true quality of contractor performance cannot be measured until the end of the contract, only the last evaluation is final. At that point, the total contract award fee pool is available, and the contractor's total performance is evaluated against the award fee plan to determine total earned award fee. In addition, interim evaluations are done to monitor performance prior to contract completion and provide feedback to the contractor on the Government's assessment of the quality of its performance. Interim evaluations are also used to establish the basis for making interim award fee payments. These interim payments are superseded by the fee determination made in the final evaluation at contract completion. The Government will then pay the contractor, or the contractor will refund to the Government, the difference between the final award fee determination and the cumulative interim fee payment.

(c) Provisional award fee payments, i.e., payments made within evaluation periods, may be included in the contract and should be negotiated on a case-by-case basis. The amount of the provisional award fee payment is determined by applying the lesser of the prior period's interim evaluation score (see 1816.404–275) or 80 percent of the fee allocated to the current period. The provisional award fee payments are superseded by the fee determinations made at the conclusion of each award fee performance period.

(d) The Fee Determination Official's rating for both interim and final evaluations will be provided to the contractor within 45 calendar days of the end of the period being evaluated. Any fee, interim or final, due the contractor will be paid no later than 60 calendar days after the end of the period being evaluated.

1816.404–274 Award fee evaluation factors.

(a) Explicit evaluation factors shall be established for each award fee period.

(b) Evaluation factors will be developed by the contracting officer based upon the characteristics of an individual procurement. Normally, technical and schedule considerations will be included in all CPAF contracts as evaluation factors. Cost control shall be included as an evaluation factor in all CPAF contracts. When explicit evaluation factor weightings are used, cost control shall be no less than 25 percent of the total weighted evaluation factors. the predominant consideration of the cost control evaluation should be a measurement of the contractor's performance against the negotiated estimated cost of the contract. This estimated cost may include the value of undefinitized change orders when appropriate.

(c) In rare circumstances, contract costs may increase for reasons outside the contractor's control and for which the contractor is not entitled to an equitable adjustment. One example is a weather-related launch delay on a launch support contract. The Government shall take such situations into consideration when evaluating contractor cost control.

(d) Emphasis on cost control should be balanced against other performance requirement objectives. The contractor should not be incentivized to pursue cost control to the point that overall performance is significantly degraded. For example, incentivizing an underrun that results in direct negative impacts on technical performance, safety, or other critical contract objectives is both undesirable and counterproductive. Therefore, evaluation of cost control shall conform to the following guidelines:

(1) Normally, the contractor should be given a score of 0 for cost control when there is a significant overrun within its control. However, the contractor may receive higher scores for cost control if the overrun is insignificant. Scores should decrease sharply as the size of the overrun increases. In any evaluation of contractor overrun performance, the Government shall consider the reasons for the overrun and assess the extend and effectiveness of the contractor's efforts to control or mitigate the overrun.

(2) The contractor should normally be rewarded for an underrun within its control, up to the maximum score allocated for cost control, provided the average numerical rating for all other award fee evaluation factors is 81 or greater (see 1816.404–275). An underrun shall be rewarded as if the contractor has met the estimated cost of the contract (see 1816.404–274(d)(3)) when the average numerical rating for all other factors is less than 81 but greater than 60.

(3) The contractor should be rewarded for meeting the estimated cost of the contract, but not to the maximum score allocated for cost control, to the degree that the contractor has prudently managed costs while meeting contract requirements. No award shall be given in this circumstance unless the average numerical rating for all other award fee evaluation factors is 61 or greater.

(e) When an AF arrangement is used in conjunction with a performance based contract structure (see 1816.404–270(b)(2)(iii)), the award fee's cost control factor will only apply to a subjective assessment of the contractor's efforts to control costs and not the actual cost outcome incentivized under the basic contract type (e.g. CPIF, FPIF).

(f) Only the award fee performance evaluation factors set forth in the performance evaluation plan shall be used to determine award fee scores.

(g) The Government may unilaterally modify the applicable award fee performance evaluation factors and performance evaluation areas prior to the start of an evaluation period. The contracting officer shall notify the contractor in writing of any such changes 30 days prior to the start of the start of the relevant evaluation period.

1816.404–275 Award fee evaluation scoring.

(a) A scoring system of 0–100 shall be used for all award fee ratings. Award fee earned is determined by applying the numerical score to the award fee pool. For example, a score of 85 yields an award fee of 85 percent of the award fee pool. No award fee shall be paid unless the total score is 61 or greater.

(b) The following standard adjectival ratings and the associated numerical scores shall be used on all award fee contracts.

(1) *Excellent* (100–91): Of exceptional merit; exemplary performance in a timely, efficient, and economic manner;

very minor (if any) deficiencies with no adverse effect on overall performance.

(2) *Very good* (90–81): Very effective performance, fully responsive to contract requirements accomplished in a timely, efficient, and economical manner for the most part; only minor deficiencies.

(3) *Good* (80–71): Effective performance; fully responsive to contract requirements; reportable deficiencies, but with little identifiable effect on overall performance.

(4) *Satisfactory* (70–61): Meets or slightly exceeds minimum acceptable standards; adequate results; reportable deficiencies with identifiable, but not substantial, effects on overall performance.

(5) *Poor/Unsatisfactory* (less than 61): Does not meet minimum acceptable standards in one or more areas; remedial action required in one or more areas; deficiencies in one or more areas which adversely affect overall performance.

(c) As a benchmark for evaluation, in order to be rated ''Excellent,'' the contractor must be under cost, on or ahead of schedule, and have provided excellent technical performance.

(d) A scoring system appropriate for the circumstances of the individual contract requirement should be developed. Weighted scoring is recommended. In this system, each evaluation factor (e.g., technical, schedule, cost control) is assigned a specific percentage weighting with the cumulative weightings of all factors totaling 100. During the award fee evaluation, each factor is scored from 0–100 according to the ratings defined in 1816.404–275(b). The numerical score for each factor is then multiplied by the weighting for that factor to determine the weighted score. For example, if the technical factor has a weighting of 60 percent and the numerical score for that factor is 80, the weighted technical score is 48 (80×60 percent). The weighted scores for each evaluation factor are then added to determine the total award fee score.

1816.405 Contract clauses.

1816.405–70 NASA contract clauses.

(a) As authorized by FAR 16.405(e), the contracting officer shall insert the clause at 1852.216–76, Award Fee for Service Contracts, in solicitations and contracts when a cost-plus-award-fee contract is contemplated and the contract deliverable is the performance of a service. When provisional award fee payments are authorized, use Alternate I.

(b) As authorized by FAR 16.405(e), the contracting officer shall insert the clause at 1852.216–77, Award Fee for End Item Contracts, in solicitations and contracts when a cost-plus-award-fee contract is contemplated and the contract deliverables are hardware or other end items for which total contractor performance cannot be measured until the end of the contract.

(c) The contracting officer may insert a clause substantially as stated at 1852.216–83, Fixed Price Incentive, in fixed-price-incentive solicitations and contracts utilizing firm or successive targets. For items subject to incentive price revision, identify the target cost, target profit, target price, and ceiling price for each item.

(d) The contracting officer shall insert the clause at 1852.216–84, Estimated Cost and Incentive Fee, in cost-plus-incentive-fee solicitations and contracts.

(e) The contracting officer may insert the clause at 1852.216–85, Estimated Cost and Award Fee, in cost-plus-award-fee solicitations and contracts. When the contract includes performance incentives, use Alternate I.

(f) As provided at 1816.402–270, the contracting officer shall insert a clause substantially as stated at 1852.216–88, Performance Incentive, when the primary deliverable(s) is (are) hardware and total estimated cost and fee is greater than $25 million. A clause substantially as stated at 1852.216–88 may be included in lower dollar value hardware contracts with the approval of the procurement officer.

Subpart 1816.5—Indefinite-Delivery Contracts

1816.504 Indefinite quantity contracts. (NASA supplements paragraph (a))

(a)(4)(ii) ID/IQ service contract values and task order values shall be expressed only in dollars.

1816.505 Ordering. (NASA supplements paragraphs (a) and (b))

(a)(2) Task and delivery orders shall be issued by the contracting officer.

(b)(4) The Agency and installation ombudsmen designated in accordance with 1815.70 shall review complaints from contractors on task order contracts and delivery order contracts.

1816.505–70 Task ordering.

(a) The contracting officer shall, to the maximum extent possible, state task order requirements in terms of functions and the related performance and quality standards such that the standards may be objectively measured.

(b) To the maximum extent possible, contracting officers shall solicit contractor task plans to use as the basis for finalizing task order requirements and enable evaluation and pricing of the contractor's proposed work on performance based approach as described in 1816.404–270(a).

(c) Task order contract type shall be individually determined, based on the nature of each task order's requirements.

(1) Task orders may be grouped by contract type for administrative convenience (e.g., all CPIF orders, all FFP orders, etc.) for contractor progress and cost reporting.

(2) Under multiple awards, solicitations for individual task plans shall request the same pricing structure from all offerors. (d) Any undefinitized task order issued under paragraph (f) of the clause at 1852.216–80, Task Ordering Procedure, shall be treated and reported as an undefinitized contract action in accordance with 1843–70.

1816.506–70 NASA contract clause.

Insert the clause at 1852.216–80, Task Ordering Procedure, in solicitations and contracts when an indefinite-delivery, task order contract is contemplated. The clause is applicable to both fixed-price and cost-reimbursement type contracts. If the contract does not require 533M reporting (See NHB 9501.2), use the clause with its Alternate I.

Subpart 1816.6—Time-and-Materials, Labor-Hour, and Letter Contracts

1816.603 Letter contracts.

1816.603–370 Approvals.

(a) All requests for authority to issue a letter contract shall include the following:

(1) Proposed contractor's name and address.

(2) Location where contract is to be performed.

(3) Contract number, including modification number, if applicable.

(4) Brief description of the work or services to be performed.

(5) Performance period or delivery schedule.

(6) Amount of letter contract.

(7) Performance period of letter contract.

(8) Estimated total amount of definitive contract.

(9) Type of definitive contract to be executed.

(10) A statement that the definitive contract will contain all required clauses or identification of specific clause deviations that have been approved.

(11) A statement as to the necessity and advantage to the Government of the proposed letter contract.

(12) The definitization schedule described in FAR 16.603–2(c) expected to be negotiated with the contractor.

(b) Requests for authority to issue letter contracts having an estimated

definitive contract amount equal to or greater than the Master Buy Plan submission thresholds of 1807.7101 (or modifications thereto) shall be signed by the procurement officer and submitted to the Associate Administrator for Procurement (Code HS) for approval.

(c) Authority to approve the issuance of letter contracts below the Master Buy Plan submission thresholds specified in 1807.7101 is delegated to the procurement officer.

(d) Any modification of an undefinitized letter contract approved by a procurement officer in accordance with (c) of this section that increases the estimated definitized contract amount to or above the Master Buy Plan submission threshold must have the prior approval of the Associate Administrator for Procurement (Code HS).

PART 1852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

1852.215–70, 1852.215–71, 1852.215–72 [Removed]

4.–5. Sections 1852.215–70, 1852.215–71 and 1852.215–72 are removed.

1852.215–73, 1852.215–74, 1852.215–75 [Revised]

6. Sections 1852.215–73, 1852.215–74 and 1852.215–75 are revised to read as follows:

1852.215–73 Late Submissions, Modifications, and Withdrawals of Proposals (AO, SBIR, and STTR Programs).

As prescribed in 1815.407–70(a), insert the following provision:

Late Submissions, Modifications, and Withdrawals of Proposals (AO, SBIR, and STTR Programs); (October 1996)

(a) The Government reserves the right to consider proposals or modifications, including any revision of an otherwise successful proposal, received after the date indicated for receipt of proposals if it would be in the Government's best interest to do so.

(b) Proposals may be withdrawn by written notice or telegram (including mailgram) received at any time before award. Proposals may be withdrawn in person by an offeror or an authorized representative, if the representative's identity is made known and the representative signs a receipt for the proposal before award.

(End of provision)

1852.215–74 Alternate Proposals.

As prescribed in 1815.407–70(b), insert the following provision:

Alternate Proposals (October 1996)

(a) The offeror may submit an alternate proposal to accomplish any aspect of the effort or product contemplated by the solicitation in a manner that might create a beneficial improvement to the Government. The Government will consider an alternate proposal if it is accompanied by a basic proposal prepared in accordance with instructions contained in this solicitation. The alternate proposal must be complete by itself and comply with the proposal instructions of this solicitation. The alternate proposal will be evaluated in accordance with the evaluation factors of this solicitation.

(b) In the event the Government receives an alternate proposal that, if accepted, would result in a contract with terms varying in one or more material respects from those contained in this solicitation, and the government concludes that implementation of the approach contained in the alternate proposal would be in its best interests, the Government may modify its solicitation in a manner appropriate to incorporate the changes but not reveal the substance of the alternate proposal, and thereafter give all offerors (and others if the facts warrant) an opportunity to respond to the modified solicitation.

(End of provision)

1852.215–75 Expenses Related to Offeror Submissions.

As prescribed in 1815.407–70(c), insert the following provision:

Expenses Related to Offeror Submissions (December 1988)

This solicitation neither commits the Government to pay any cost incurred in the submission of the offer or in making necessary studies or designs for preparing the offer, nor to contract for services or supplies. any costs incurred in anticipation of a contract shall be at the offeror's own risk.

(End of provision)

1852.215–76 [Removal]

7. Section 1852.215–76 is removed.

8. Sections 1852.215–77, 1852.215–78 and 1852.215–79 are revised to read as follows:

1852.215–77 Preproposal/Pre-bid Conference.

As prescribed in 1815.407–70(d), insert the following provision:

Preproposal/Pre-Bid Conference (December 1988)

(a) A preproposal/pre-bid conference will be held as indicated below:

Date:
Time:
Location:
Other Information, as applicable:

(Insert the applicable conference information.)

(b) Attendance at the preproposal/pre-bid conference is recommended; however, attendance is neither required nor a prerequisite for proposal/bid submission and will not be considered in the evaluation.

(End of provision)

1852.215–78 Make or Buy Program Requirements.

As prescribed in 1815.708–70(a), insert the following provision:

Make or Buy Program Requirements (December 1988)

The offeror shall submit a Make-or-Buy Program in accordance with the requirements of Federal Acquisition Regulation (FAR) 15.705. The offeror shall include the following supporting documentation with its proposal:

(a) A description of each major item or work effort (see FAR 15.704).

(b) Categorization of each major item or work effort as ''must make,'' ''must buy,'' or ''can either make or buy.''

(c) For each item or work effort categorized as ''can either make or buy,'' a proposal either to ''make'' or ''buy.''

(d) Reasons for (i) categorizing items and work effort as ''must make'' or ''must buy'' and (ii) proposing to ''make'' or ''buy'' those categorized as ''can either make or buy.'' The reasons must include the consideration given to the applicable evaluation factors described in the solicitation and be in sufficient detail to permit the Contracting Officer to evaluate the categorization and proposal.

(e) Designation of the offeror's plant or division proposed to make each item or perform each work effort and a statement as to whether the existing or proposed new facility is in or near a labor surplus area.

(f) Identification of proposed subcontractors, if known, and their location and size status.

(g) Any recommendations to defer make-or-buy decisions when categorization of some items or work efforts is impracticable at the time of submission.

(End of provision)

1852.215–79 Price Adjustment for ''Make-or-Buy'' Changes.

As prescribed in 1815.708–70(b), insert the following clause:

Price Adjustment for ''Make-or-Buy'' Changes (December 1988)

The following make-or-buy items are subject to the provisions of paragraph (d) of the clause at FAR 52.215–21, Change or Additions to Make-or-Buy Program, of this contract:

Item Description

Make-or-Buy Determination

(End of clause)

1852.215–80 [Removed]

8. Section 1852.215–80 is removed.

9. Sections 1852.215–81 and 1852.215–82 are revised to read as follows:

1852.215–81 Proposed Page Limitations.

As prescribed in 1815.407–70(g), insert the following provision:

Proposal Page Limitations (January 1994)

(a) The following page limitations are established for each portion of the proposal submitted in response to this solicitation.

Proposed Section (List each volume or section)	Page Limit (Specify limit)
	....

(b) A page is defined as one side of a sheet, 8½″ × 11″, with at least one inch margins on all sides, using not smaller than 12 characters per inch (or equivalent) type. Foldouts count as an equivalent number of 8½″ × 11″ pages. The metric standard format most closely approximating the described standard 8½″ × 11″ size may also be used.

(c) Title pages and tables of contents are excluded from the page counts specified in paragraph (a) of this provision. In addition, the Cost section of your proposal is not page limited. However, this section is to be strictly limited to cost and price information. Information that can be construed as belonging in one of the other sections of the proposal will be so construed and counted against that section's page limitation.

(d) If Best and Final Offers (BAFOs) are requested, separate page limitations will be specified in the Government's request for that submission.

(e) Pages submitted in excess of the limitations specified in this provision will not be evaluated by the Government and will be returned to the offeror.

(End of provision)

1852.215–82 Offeror Oral Presentations.

As prescribed in 1815.407–70(h), insert the following provision:

Offeror Oral Presentations (November 1993)

(a) Offerors are invited to give an oral presentation to the Government on the structure and general content of their proposals. These presentations are intended to assist Government evaluation by providing a ''roadmap'' to understanding proposals, i.e., an overview of the proposal organization and layout, and where required information and elements are located. Although the offeror's basic approach to satisfying solicitation requirements may be explained, it is to be done so only in general terms and only to expedite the Government's formal evaluation.

(b) The Government will not engage in any discussions during the oral presentation, and no proposal revisions will be accepted as part of the presentation. The Government's evaluation of offeror proposals will be based on the contents of the initial proposal, and any information not included in the initial proposal that is provided at the oral presentation will not be evaluated.

(c) Offerors should indicate in their proposals if they wish to give an oral presentation. These presentations are not mandatory, and electing not to give a presentation will not, in itself, affect proposal evaluation.

(d) Because the presentations are intended to assist the Government's evaluation, they will be scheduled to take place prior to commencement of the formal initial evaluation, normally within three days after proposal receipt. Offerors unable to accommodate this schedule forfeit their opportunity to provide a presentation.

(e) The presentations will consist of an offeror briefing not to exceed ____ (insert 1 or 2) hours to be followed by a question and answer period. The order of offeror presentations will be determined at random. The exact time and place of the presentation, along with any other guidance, will be provided to the offeror by the contracting officer or his/her representative.

(f) Presentation materials are not required, but if used, the Government will retain one copy in its official file as a historical record of the presentation even though these materials will not be used in the Government's evaluation process.

(End of provision)

1852.215–83 [Removed]

10. Section 1852.215–83 is removed.

1852.215–84 [Amended]

11. As prescribed in 1815.7003, insert the following clause:

Ombudsman (October 1996)

An ombudsman has been appointed to hear and facilitate the resolution of concerns from offerors, potential offerors, and contractors during the preaward and postaward phases of this acquisition. When requested, the ombudsman will maintain strict confidentiality as to the source of the concern. The existence of the ombudsman is not to diminish the authority of the contracting officer, the Source Evaluation Board, or the selection official. Further, the ombudsman does not participate in the evaluation of proposals, the source selection process, or the adjudication of formal contract disputes. Therefore, before consulting with an ombudsman, interested parties must first address their concerns, issues, disagreements, and/or recommendations to the contracting officer for resolution. If resolution cannot be made by the contracting officer, interested parties may contact the installation ombudsman, _____ (Insert name), at _____ (Insert telephone number).

Concerns, issues, disagreements, and recommendations which cannot be resolved at the installation may be referred to the NASA ombudsman, the Deputy Administrator for Procurement, at 202–358–2090. Please do not contact the ombudsman to request copies of the solicilation, verify offer due date, or clarify technical requirements. Such inquiries shall be directed to the contracting officer or as specified elsewhere in this document.

(End of clause)

1852.216–72 [Removed]

12. Section 1852.216–72 is removed.

13. Sections 1852.216–73, 1852.216–74, 1852.216–75, 1852.216–76, 1852.216–77 and 1852.216–78 are revised to read as follows:

1852.216–73 Estimated cost and cost sharing.

As prescribed in 1816.307–70(a), insert the following clause:

Estimated Cost and Cost Sharing (December 1991)

(a) It is estimated that the total cost of performing the work under this contract will be $____

(b) For performance of the work under this contract, the Contractor shall be reimbursed for not more than ____ percent of the costs of performance determined to be allowable under the Allowable Cost and Payment clause. The remaining ____ percent or more of the costs of performance so determined shall constitute the Contractor's share, for which it will not be reimbursed by the Government.

(c) For purposes the _____ (insert ''Limitation of Cost'' or ''Limitation of Funds'') clause, the total estimated cost to the Government is hereby established as $____ (insert estimated Government share); this amount is the maximum Government liability.

(d) The Contractor shall maintain records of all contract costs claimed by the Contractor as constituting part of its share. Those records shall be subject to audit by the Government. Costs contributed by the Contractor shall not be charged to the Government under any other grant, contract, or agreement (including allocation to other grants, contracts, or agreements as part of an independent research and development program).

(End of clause)

1852.216–74 Estimated Cost and Fixed Fee.

As prescribed in 1816.307–70(b), insert the following clause:

Estimated Cost and Fixed Fee (December 1991)

The estimated cost of this contract is ____ exclusive of the fixed fee of ____. The total estimated cost and fixed fee is ____.

(End of clause)

1852.216–75 Payment of Fixed Fee.

As prescribed in 1816.307–70(c), insert the following clause:

Payment of Fixed Fee (December 1988)

The fixed fee shall be paid in monthly installments based upon the percentage of completion of work as determined by the Contracting Officer.

(End of clause)

1852.216–76 Award Fee for Service Contracts.

As prescribed in 1816.405–70(a), insert the following clause:

Award Fee for Service Contracts (October 1996)

(a) The contractor can earn award fee from a minimum of zero dollars to the maximum stated in NASA FAR Supplement clause 1852.216–85, ''Estimated Cost and Award Fee'' in this contract.

(b) Beginning 6 [1] months after the effective date of this contract, the Government shall

[1] (A period of time greater or lesser than 6 months may be substituted in accordance with 18–16.404–272(a).)

evaluate the Contractor's performance every 6 months to determine the amount of award fee earned by the contractor during the period. The Contractor may submit a self-evaluation of performance for each evaluation period under consideration. These self-evaluations will be considered by the Government in its evaluation. The Government's Fee Determination Official (FDO) will determine the award fee amounts based on the Contractor's performance in accordance with *(identify performance evaluation plan).* The plan may be revised unilaterally by the Government prior to the beginning of any rating period to redirect emphasis.

(c) The Government will advise the Contractor in writing of the evaluation results. The *(insert payment office)* will make payment based on *(Insert method of authorizing award fee payment, e.g., issuance of unilateral modification by contracting officer).*

(d) After 85 percent of the potential award fee has been paid, the Contracting Officer may direct the withholding of further payment of award fee until a reserve is set aside in an amount that the Contracting Officer considers necessary to protect the Government's interest. This reserve shall not exceed 15 percent of the total potential award fee.

(e) The amount of award fee which can be awarded in each evaluation period is limited to the amounts set forth at *(identify location of award fee amounts).* Award fee which is not earned in an evaluation period cannot be reallocated to future evaluation periods.

(f) Award fee determinations made by the Government under this contract are not subject to the Disputes clause.

Alternate I (October 1996)

As prescribed in 1816.405–70(a), insert the following paragraph (f) and reletter existing paragraph (f) to (g):

(f) (1) Pending a determination of the amount of award fee earned for an evaluation period, a portion of the available award fee for that period will be paid to the contractor on a (*Insert the frequency of provisional payments (not more often than monthly*)) basis. The portion paid will be ____ (insert percentage (not to exceed 80 percent)) percent of the current period's available amount or the equivalent of the prior period's interim fee, whichever is lower; provided, however, that when the Contracting Officer determines that the Contractor will not achieve a level of performance commensurate with the provisional rate, payment of provisional award fee will be discontinued or reduced in such amounts as the Contracting Officer deems appropriate. The Contracting Officer will notify the Contractor in writing if it is determined that such discontinuance or reduction is appropriate. This determination is not subject to the Disputes clause.

(2) In the event the amount of award fee earned, as determined by the FDO, is less than the sum of the provisional payments made for that period, the Contractor will either credit the next payment voucher for the amount of such overpayment or refund the difference to the Government, as directed by the Contracting Officer.

(3) Provisional award fee payments will (*insert ''not'' if appropriate*) be made prior to the first award fee determination by the Government.

(End of clause)

1852.216–77 Award Fee for End Item Contracts.

As prescribed in 1816.405–70(b), insert the following clause:

Award Fee for End Item Contracts (October 1996)

(a) The contractor can earn award fee, or base fee, if any, from a minimum of zero dollars to the maximum stated in NASA FAR Supplement clause 1852.216–85, ''Estimated Cost and Award Fee'' in this contract. All award fee evaluations, with the exception of the last evaluation, will be interim evaluations. At the last evaluation, which is final, the Contractor's performance for the entire contract will be evaluated to determine total earned award fee. No award fee or base fee will be paid to the Contractor if the final award fee evaluation is ''poor/unsatisfactory.''

(b) Beginning 6 [1] months after the effective date of this contract, the Government will evaluate the Contractor's interim performance every 6 [1] months to monitor Contractor performance prior to contract completion and to provide feedback to the Contractor. The evaluation will be performed in accordance with (*identify performance evaluation plan*) to this contract. The Contractor may submit a self-evaluation of performance for each period under consideration. These self-evaluations will be considered by the Government in its evaluation. The Government will advise the Contractor in writing of the evaluation results. The plan may be revised unilaterally by the Government prior to the beginning of any rating period to redirect emphasis.

(c) (1) Base fee, if applicable, will be paid in (*Insert ''monthly'', or less frequent period*) installments based on the percent of completion of the work as determined by the Contracting Officer.

(2) Interim award fee payments will be made to the Contractor based on each interim evaluation. The amount of the interim award fee payment is limited to the lesser of the interim evaluation score or 80 percent of the fee allocated to that period *less* any provisional payments made during the period. All interim award fee payments will be superseded by the final award fee determination.

(3) Provisional award fee payments will (*insert ''not'' if applicable*) be made under this contract pending each interim evaluation. If applicable, provisional award fee payments will be made to the Contractor on a (*insert the frequency of provisional payments (not more often than monthly*)) basis. The amount of award fee which will be provisionally paid in each evaluation period is limited to (Insert a percent not to exceed 80 percent) of the prior interim evaluation score (see (*insert applicable cite*)). Provisional award fee payments made each evaluation period will be superseded by the interim award fee evaluation for that period. If provisional payments made exceed the interim evaluation score, the Contractor will either credit the next payment voucher for the amount of such overpayment or refund the difference to the Government, as directed by the Contracting Officer. If the Government determines that (i) the total amount of provisional fee payments will apparently *substantially* exceed the anticipated final evaluation score, or (ii) the prior interim evaluation is ''poor/unsatisfactory,'' the Contracting Officer will direct the suspension or reduction of the future payments and/or request a prompt refund of excess payments as appropriate. Written notification of the determination will be provided to the Contractor with a copy to the Deputy Chief Financial Officer (Finance). This determination is not subject to the Disputes clause.

(4) All interim (and provisional, if applicable) fee payments will be superseded by the fee determination made in the final award fee evaluation. The Government will then pay the Contractor, or the Contractor will refund to the Government the difference between the final award fee determination and the cumulative provisional fee payments. If the final award fee evaluation is ''poor/unsatisfactory,'' any base fee paid will be refunded to the Government.

(5) Payment of base fee, if applicable, will be made based on submission of an invoice by the Contractor. Payment of award fee will be made by the *(insert payment office)* based on *(insert method of making award fee payment, e.g., issuance of a unilateral modification by the Contracting Officer).*

(d) Award fee determinations made by the Government under this contract are not subject to the Dispute clause.

(End of clause)

1852.216–78 Firm Fixed price.

As prescribed in 1816.202–70, insert the following clause:

Firm Fixed Price (December 1988)

The total firm fixed price of this contract is $____ (insert the appropriate amount).

(End of clause)

1852.216–79 [Removed]

14. Section 1852.216–79 is removed.

15. Sections 1852.216–80 and 1852.216–81 are revised to read as follows:

1852.216–80 Task Ordering Procedure.

As prescribed in 1816.506–70, insert the following clause:

Task Ordering Procedure (October 1996)

(a) Only the Contracting Officer may issue task orders to the Contractor, providing specific authorization or direction to perform work within the scope of the contract and as specified in the schedule. The Contractor may incur costs under this contract in performance of task orders and task order modifications issued in accordance with this

[1] (A period of time greater or lesser than 6 months may be substituted in accordance with 1816.404–272(a).)

clause. No other costs are authorized unless otherwise specified in the contract or expressly authorized by the Contracting Officer.

(b) Prior to issuing a task order, the Contracting Officer shall provide the Contractor with the following data:

(1) A functional description of the work identifying the objectives or results desired from the contemplated task order.

(2) Proposed performance standards to be used as criteria for determining whether the work requirements have been met.

(3) A request for a task plan from the Contractor to include the technical approach, period of performance, appropriate cost information, and any other information required to determine the reasonableness of the Contractor's proposal.

(c) Within ____ calendar days after receipt of the Contracting Officer's request, the Contractor shall submit a task plan conforming to the request.

(d) After review and any necessary discussions, the Contracting Officer may issue a task order to the Contractor containing, as a minimum, the following:

(1) Date of the order.

(2) Contract number and order number.

(3) Functional description of the work identifying the objectives or results desired from the task order, including special instructions or other information necessary for performance of the task.

(4) Performance standards, and where appropriate, quality assurance standards.

(5) Maximum dollar amount authorized (cost and fee or price). This includes allocation of award fee among award fee periods, if applicable.

(6) Any other resources (travel, materials, equipment, facilities, etc.) authorized.

(7) Delivery/performance schedule including start and end dates.

(8) If contract funding is by individual task order, accounting and appropriation data.

(e) The Contractor shall provide acknowledgment of receipt to the Contracting Officer within __ calendar days after receipt of the task order.

(f) If time constraints do not permit issuance of a fully defined task order in accordance with the procedures described in paragraphs (a) through (d), a task order which includes a ceiling price may be issued.

(g) The Contracting Officer may amend tasks in the same manner in which they were issued.

(h) In the event of a conflict between the requirements of the task order and the Contractor's approved task plan, the task order shall prevail.

(End of clause)

Alternate I (October 1996)

As prescribed in 1816.506–70, insert the following paragraph (i) if the contract does not include 533M reporting:

(i) Contractor shall submit monthly task order progress reports. As a minimum, the reports shall contain the following information:

(1) Contract number, task order number, and date of the order.

(2) Task ceiling price.

(3) Cost and hours incurred to date for each issued task.

(4) Costs and hours estimated to complete each issued task.

(5) Significant issues/problems associated with a task.

(6) Cost summary of the status of all tasks issued under the contract.

1852.216–81 Estimated Cost.

As prescribed in 1816.307–70(d), insert the following clause:

Estimated Cost (December 1988)

The total estimated cost for complete performance of this contract is $____ (Insert total estimated cost of the contract). See FAR clause 52.216–11, Cost Contract—No Fee, of this contract.

(End of clause)

1852.216–82 [Removed]

16. Section 1852.216–82 is removed.

17. Sections 1852.216–83, 1852.216–84 and 1852.216–85 are revised to read as follows:

1852.216–83 Fixed Price Incentive.

As prescribed in 1816.405–70(c), insert the following clause:

Fixed Price Incentive (October 1996)

The target cost of this contract is $____ The Target profit of this contract is $____. The target price (target cost plus target profit) of this contract is $____. [The ceiling price is $____.]

The cost sharing for target cost underruns is:

Government ____ percent Contractor ____ percent.

The cost sharing for target cost overruns is:

Government ____ percent Contractor ____ percent.

(End of clause)

1852.216–84 Estimated Cost and Incentive Fee.

As prescribed in 1816.405–70(d), insert the following clause:

Estimated Cost and Incentive Fee (October 1996)

The target cost of this contract is $____. The target fee of this contract is $____. The total target cost and target fee as contemplated by the Incentive Fee clause of this contract are $____.

The maximum fee is $____.

The minimum fee is $____.

The cost sharing for cost underruns is: Government ____ percent Contractor ____ percent.

The cost sharing for cost overruns is: Government ____ percent Contractor ____ percent.

(End of clause)

1852.216–85 Estimated Cost and Award Fee.

As prescribed in 1816.405–70(e), insert the following clause:

Estimated Cost and Award Fee (September 1993)

The estimated cost of this contract is $____. The maximum available award fee, excluding base fee, if any, is $____. The base fee is $____. Total estimated cost, base fee, and maximum award fee are $____.

(End of clause)

Alternate I (September 1993)

As prescribed in 1816.405–70(e), insert the following sentence at the end of the clause:

The maximum positive performance incentive is $____. The maximum negative performance incentive is (1).

(1) For research development hardware contracts, insert [equal to total earned award fee (including any base fee)]. For production hardware contracts, insert (*$ total potential award fee amount, including any base fee).*

(End of clause)

1852.216–86 [Removed]

18. Section 1852.216–86 is removed.

1852.216–87, 1852.216–88, 1852.216–89 [Revised]

19. Sections 1852.216–87, 1852.216–88 and 1852.216–89 are revised to read as follows:

1852.216–87 Submission of Vouchers for Payment.

As prescribed in 1816.307–70(e), insert the following clause:

Submission of Vouchers for Payment (December 1988)

(a) Public vouchers for payment of costs shall include a reference to this contract (Insert the contract *number*) and be forwarded to: (Insert the mailing address for submission of cost vouchers.)

This is the designated billing office for cost vouchers for purposes of the Prompt Payment clause of this contract.

(b) The Contractor shall prepare vouchers as follows:

(1) One original Standard Form (SF) 1034, SR 1035, or equivalent Contractor's attachment.

(2) Seven copies of SF 1034A, SF1035A, or equivalent Contractor's attachment.

(3) The Contractor shall mark SF 1034A copies 1, 2, 3, 4, and such other copies as may be directed by the Contracting Officer by insertion in the memorandum block the names and addresses as follows:

(i) Copy 1 NASA Contracting Officer;

(ii) Copy 2 Auditor;

(iii) Copy 3 Contractor;

(iv) Copy 4 Contract administration office; and

(v) Copy 5 Project management office.

(c) Public vouchers for payment of fee shall be prepared similarly and be forwarded to: (Insert the mailing address for submission of fee vouchers.)

This is the designated billing office for fee vouchers for purposes of the Prompt Payment clause of this contract.

(d) In the event that amounts are withheld from payment in accordance with provisions of this contract, a separate voucher for the amount withheld will be required before payment for that amount may be made.

1852.216–88 Performance Incentive.

As prescribed in 1816.405–70(f), insert the following clause:

Performance Incentive (October 1996)

(a) A performance incentive applies to the following hardware item(s) delivered under this contract: (1)

The performance incentive will measure the performance of those items against the salient hardware performance requirement, called ''unit(s) of measurement,'' e.g., months in service or amount of data transmitted, identified below. The performance incentive becomes effective when the hardware is put into service. It includes a standard performance level, a positive incentive, and a negative incentive, which are described in this clause.

(b) Standard performance level. At the standard performance level, the Contractor has met the contract requirement for the unit of measurement. Neither positive nor negative incentives apply when this level is achieved but not exceeded. The standard performance level for (1) __ is established as follows: (2)

(c) Positive incentive. The Contractor earns a separate positive incentive amount for each hardware item listed in paragraph (a) of this clause when the standard performance level for that item is exceeded. The amount earned for each item varies with the units of measurement achieved, up to a maximum positive performance incentive amount of $xx (3) x per item. The units of measurement and the incentive amounts associated with achieving each unit are shown below: (4)

(d) Negative incentive. The Contractor will pay to the Government a negative incentive amount for each hardware item that fails to achieve the standard performance level. The amount to be paid for each item varies with the units of measurement achieved, up to the maximum negative incentive amount of $ (5) x. The units of measurement and the incentive amounts associated with achieving each unit are shown below: (6)

(e) The final calculation of positive or negative performance incentive amounts shall be done with performance (as defined by the unit of measurement) ceases or when the maximum positive incentive is reached.

(1) When the Contracting Officer determines that the performance level achieved fell below the standard performance level, the Contractor will either pay the amount due the Government or credit the next payment voucher for the amount due, as directed by the Contracting Officer.

(2) When the performance level exceeds the standard level, the Contractor may request payment of the incentive amount associated with a given level of performance, provided that such payments shall not be more frequent than monthly. When performance ceases or the maximum positive incentive is reached, the Government shall calculate the final performance incentive earned and unpaid and promptly remit it to the contractor.

(f) If performance cannot be demonstrated, through no fault of the Contractor, within (insert number of months or years) after the date of hardware acceptance by the Government, the Contractor will be paid (insert percentage) of the maximum performance incentive.

(g) The decisions made as to the amount(s) of positive or negative incentives are subject to the Disputes clause.

(1) Insert applicable item number(s) and/or nomenclature.

(2) Insert a specific unit of measurement for each hardware item listed in (1) and each salient characteristic, if more than one.

(3) Insert the maximum positive performance incentive amount (see 1816.402–270(e) (1) and (2)).

(4) Insert all units of measurement and associated dollar amounts up to the maximum performance incentive.

(5) For research and development hardware contracts, insert (equal to total earned award fee (including any base fee)). For production hardware contracts, insert ($____ (total potential award fee amount, including any base fee)) (see 1816.402–270(2)(ii)).

(6) Insert all units of measurement and associated dollar amounts up to the maximum negative performance incentive.

(End of clause)

1852.216–89 Assignment and Release Forms.

As prescribed at 1816.307–70(f), insert the following clause:

Assignment and Release Forms (October 1996)

The Contractor shall use the following forms to fulfill the assignment and release requirements of FAR Clause 52.216–7, Allowable Cost and Payment, and FAR Clause 52.216–13, Allowable Cost and Payment (Facilities):

NASA Form 778, Contractor's Release
NASA Form 779, Assignee's Release
NASA Form 780, Contractor's Assignment of Refunds, Rebates, Credits, and Other Amounts

Computer generated forms are acceptable, provided that they comply with FAR Clause 52.253–1.

(End of clause)

PART 1870—NASA SUPPLEMENTARY REGULATIONS

Subpart 1870.3—[Removed]

20. Subpart 1870.3, NASA Source Evaluation, is removed.

[FR Doc. 96–25189 Filed 10–4–96; 8:45 am]

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GENERAL SERVICES ADMINISTRATION

48 CFR Parts 6101 and 6102

RIN Number 3090–AF99

Board of Contract Appeals; Rules of Procedure of the General Services Administration Board of Contract Appeals: Standard Proceedings and Expedited Proceedings

AGENCY: Board of Contract Appeals, General Services Administration.

ACTION: Final rule.

SUMMARY: This document contains final revisions to the rules governing proceedings before the General Services Administration Board of Contract Appeals (Board). It supersedes the current rules of procedure of the Board which are contained in 48 CFR part 6101, in their entirety. The rules governing the standard proceedings of the Board are now contained in part 6101, while rules governing expedited proceedings—including alternative dispute resolution (ADR)—are contained in part 6102. The Board, by majority vote, has adopted these revised rules pursuant to its authority contained in the Contract Disputes Act of 1978 (41 U.S.C. 601–613). The revised rules will govern proceedings before the Board in contract appeals (41 U.S.C. 601–613), as well as any ADR proceedings handled by the Board pursuant to authority delegated by the Administrator of General Services.

EFFECTIVE DATE: October 7, 1996.

FOR FURTHER INFORMATION CONTACT: Margaret S. Pfunder, Deputy Chief Counsel, GSA Board of Contract Appeals, telephone (202) 501–0272, Internet address Margaret.Pfunder@gsa.gov..

SUPPLEMENTARY INFORMATION:

A. Regulatory Flexibility Act

The General Services Administration certifies that these revisions will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

B. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the rule does not impose recordkeeping or information collection requirements, or the collection of information from offerors, contractors, or members of the public which require the approval of OMB under 44 U.S.C. 3501 et seq.

C. Effective Dates

These rules are applicable to all proceedings filed on or after October 7, 1996. Protests and related proceedings are governed by the rules in effect at the time the underlying protests were filed.

D. Background

On June 24, 1996, the Board published in the Federal Register (61 FR 32410) a notice inviting written comments on proposed revisions to its rules of procedure. This notice announced the Board's intention to revise its existing rules of procedure, 48 CFR part 6101, and explained the purpose of the proposed revisions was to implement section 5101 of the Defense Authorization Act for Fiscal Year 1996 (Pub. L. 104–106), which eliminated the Board's jurisdiction to hear and decide bid protests which were filed on or after August 8, 1996, regarding procurements of automatic data processing (ADP) equipment and services. This final rule implements section 5101 by eliminating all references to bid protests in the Board's rules of procedure.

This rule (Part 6102) also describes the techniques intended to shorten and simplify, when appropriate, the formal proceedings used by the Board to resolve contract disputes. In particular, the rules expressly permit the use of ADR. The Board will make its services available for ADR proceedings involving any agency in contract and procurement matters at any stage, even if no contracting officer decision has been issued or is contemplated. For agencies other than GSA, The Board will provide ADR services on a reimbursable basis.

E. Summary of Comments and Changes

The Board received written comments from six commentators. Commentators included the offices of general counsel of three federal agencies, the office of the chief trial attorney of a federal agency, and one private legal practitioner. The Board carefully considered each comment, and adopted many of the suggestions made by the commentators. The more significant comments are discussed below in a section-by-section format.

Part 6101

Section 6101.4 (Appeal File): One commentator suggested that Section 6101.4(a)(6) be revised to eliminate the requirement that bid abstracts be made part of the appeal file. Abstracts are often relevant in cases alleging a mistake in bids and in vehicle auction cases in which the Government seeks to recover actual damages. Accordingly, the Board revised this provision to require that the appeal file contain the abstract of bids only ''if relevant.''

Section 6101.5 (Filing Cases; Time Limits for Filing; Docketing): One commentator suggested that since special or limited participation in a case is discretionary with the Board, it should be granted only after a motion is filed. Section 6101.5(a)(4) has been revised to make this requirement explicit.

Section 6101.6 (Appearances; Notice of Appearance): One commentator pointed out that not all agency regulations permit an agency to be represented before the Board by a contracting officer or contracting officer's authorized representative. Section 6101.6(a)(2) has been revised to permit such representation if not prohibited by ''agency regulation or otherwise.''

In accordance with the suggestion of a commentator, Section 6101.6(b) has been revised to require that attorneys representing parties before the Board list the state bars to which they are admitted and their state bar numbers or other bar identifiers in the notice of appearance.

One commentator suggested that a motion for withdrawal of appearance is unnecessary if the new attorney enters an appearance at the time of the requested withdrawal. Section 6101.6(c) has been revised to require a person who has filed a notice of appearance and who wishes to withdraw from a case to file a motion which provides the name, address, telephone number, and facsimile machine number of the person who will assume responsibility for representation of the party in question. If the motion is accompanied by a statement from the successor representative that the established case schedule will be met, the motion need not state the grounds for withdrawal.

Section 6101.7 (Pleadings in Appeals): In response to the suggestion of one commentator, Section 6101.7(b), governing the complaint, now provides that the Board may designate a notice of appeal, a claim submission, or any other document as the complaint ''if the document sufficiently states the factual basis and amount of the claim.''

Section 6101.8 (Motions): In Section 6101.8(c), the list of dispositive motions that may be made before the Board has been modified at the suggestion of one commentator to include motions to dismiss without prejudice.

Section 6101.17 (Interrogatories to Parties; Requests for Admission; Requests for Production of Documents): One commentator suggested eliminating the requirement that parties obtain permission of the Board before participating in discovery, citing an appellant's ability to use the Freedom of Information Act to obtain information. The Board determined to retain this provision, noting that early discovery may be requested by either party whenever needed, and that the provision is a useful means of monitoring case development and controlling the expenditure of effort.

Section 6101.17(c) has been revised in response to the comment that the rule does not require that answers to requests for admission be sworn. The last two sentences of Section 6101.7(c) now state that any matter admitted is conclusively established for the purpose of the pending action, unless the Board on motion permits withdrawal or amendment of the admission, and that any admission made in the case may not be used against the party making it in any other proceeding.

Section 6101.32 (Reconsideration; Amendment of Decision; New hearing) and *Section 6101.33 (Relief from Decision or Order):* One commentator suggested that these rules should clarify whether the filing of an appeal of a Board decision with the United States Court of Appeals for the Federal Circuit wrests from the Board jurisdiction to consider motions under these two sections. Similarly, the same commentator suggested clarifying that a motion pending under Section 6101.32(d) or Section 6101.33(d) tolls the time for filing an appeal with the Court of Appeals for the Federal Circuit. The Board believes that these matters are not appropriately resolved by rules of procedure. It did not modify these rules.

''Offer of Judgment'' rule: Two commentators suggested that an ''offer of judgment'' provision similar to Federal Rule of Civil Procedure 68 should be adopted by the Board. The commentators believe that the rule encourages a realistic, prompt, and thorough assessment of claims and leads to the settlement of matters in dispute between the parties. The Board knows of no statute that would permit adoption of such a rule, and therefore did not accept the suggestion.

Part 6102

Section 6102.1 (Variation from Standard Proceedings): At the suggestion of one commentator, the Board revised this rule to clarify that expedited proceedings other than small claims and accelerated procedures (Sections 6102.2 and 6102.3) are used only when the parties agree to use them, and when the Board deems such proceedings to be in the best interest of the parties, the Board, and the resolution of contract disputes.

Section 6102.4 (Alternative Dispute Resolution): Although strongly supportive of the Board's efforts to make ADR services available to parties upon request, two commentators queried whether the Board had sufficient statutory or delegated authority for this expanded role. They also suggested that the rule clarify whether these services were to be provide on a reimbursable basis.

The Administrator of General Services has delegated the needed authority to the Board. The delegation specifies that when the Board makes ADR services available to agencies other than GSA, the services will be provided on a reimbursable basis. The Section has been revised to state more clearly that the Board will make its services available for ADR proceedings involving any agency in contract and procurement matters at any stage, even if no contracting officer decision has been issued or is contemplated.

Section 6102.4(b)(1): At the suggestion of one commentator, Section 6102.4(b)(1) has been redrafted to clarify that, if ADR is agreed to by the parties and the Board, the parties may request that the Board's chairman appoint a particular judge or judges as the Neutral, or that the chairman appoint any judge or judges as the Neutral.

Two commentators suggested that, if the ADR involves a case pending before the Board, the parties should be allowed to choose whether a panel chairman who serves as a Neutral be permitted to retain the case should the ADR be unsuccessful. In response, Section 6102.4(b)(1) now provides that, if the ADR is unsuccessful and has involved mediation, the panel chairman shall not retain the case; if the ADR is unsuccessful and has not involved mediation, the panel chairman shall consider the parties' views and decide whether to retain the case.

Section 6102.4(b)(2): One commentator suggested that the Board specify what would happen to material developed during an ADR proceeding, which is not retained by the Board after the proceeding is concluded or otherwise terminated. The Board does not believe that particular procedures need be specified the rules. The Section has been revised, however, to clarify that material created by a party for the purpose of an ADR proceeding is to be used solely for that proceeding unless the parties agree otherwise.

Section 6102.4(c): In accordance with the suggestion of one commentator, this section has been revised to state that the Board will consider the use of any ADR technique propose by the parties which is deemed to be fair, reasonable, and in the best interest of the parties, the Board, and the resolution of contract disputes.

One commentator suggested that a mediator be precluded from discussing the ADR with other judges. In recognition of this concern, Section 6102.4(c)(1) has been revised to provide that no judge who has participated in discussions about a mediation will participate in a Board decision of the case if the ADR is unsuccessful.

One commentator suggested that this section should specify when ADR is most effective. Although the Board believes these considerations need not be presented in a rule, it agrees with the commentator that ADR is most effective as a dispute resolution technique when the essential elements of a successful ADR environment exist. These elements include: a genuine desire by the parties to resolve the dispute through ADR; an agreement by the parties as to the general type of ADR to be conducted and the rules to be used in conducting the ADR; and a willingness by the parties to have present at a non-binding ADR proceeding a principal with authority to agree to the settlement of the case.

List of Subjects

48 CFR Part 6101

Administrative practice and procedure, Government procurement.

48 CFR Part 6102

Administrative practice and procedure, Government procurement.

For the reasons set out in the preamble, 48 CFR chapter 61 is amended as follows:

1. Part 6101 is revised to read as follows:

PART 6101—RULES OF PROCEDURE OF THE GENERAL SERVICES ADMINISTRATION BOARD OF CONTRACT APPEALS (STANDARD PROCEEDINGS)

Sec.

6101.0 Foreword.
6101.1 Scope of rules; definitions; construction; rulings and orders; panels; situs [Rule 101].
6101.2 Time; enlargement; computation [Rule 102].
6101.3 Service of papers [Rule 103].
6101.4 Appeal file [Rule 104].
6101.5 Filing cases; time limits for filing; docketing [Rule 105].
6101.6 Appearances; notice of appearance [Rule 106].
6101.7 Pleadings in appeals [Rule 107].
6101.8 Motions [Rule 108].
6101.9 Election of hearing or record submission [Rule 109].
6101.10 Conferences; conference memorandum; prehearing order; prehearing and presubmission briefs [Rule 110].
6101.11 Submission on the record without a hearing [Rule 111].
6101.12 Record of Board proceedings [Rule 112].
6101.13 [Reserved].
6101.14 [Reserved].
6101.15 General provisions governing discovery [Rule 115].
6101.16 Depositions [Rule 116].
6101.17 Interrogatories to parties; requests for admission; requests for production of documents [Rule 117].
6101.18 Sanctions and other proceedings [Rule 118].
6101.19 Hearings: scheduling; notice; unexcused absences [Rule 119].
6101.20 Subpoenas [Rule 120].
6101.21 Hearing procedures [Rule 121].
6101.22 Admissibility and weight and evidence [Rule 122].
6101.23 Exhibits [Rule 123].
6101.24 Transcripts of proceedings; corrections [Rule 124].
6101.25 Briefs and memoranda of law [Rule 125].
6101.26 Consolidation; separate hearings; separate determination of liability [Rule 126].
6101.27 Stay of suspension of proceedings; dismissals in lieu of stay or suspension [Rule 127].
6101.28 Dismissals [Rule 128].
6101.29 Decisions: format; procedure [Rule 129].
6101.30 Full Board consideration [Rule 130].
6101.31 Clerical mistakes [Rule 131].
6101.32 Reconsideration; amendment of decisions; new hearings [Rule 132].
6101.33 Relief from decision or order [Rule 133].
6101.34 Harmless error [Rule 134].
6101.35 Award of costs [Rule 135].
6101.36 Payment of Board awards [Rule 136].
6101.37 Record on review of a Board decision [Rule 137].
6101.38 Office of the Clerk of the Board [Rule 138].

6101.39 Seal of the Board [Rule 139].
6101.40 Forms [Rule 140].
Appendix—Forms Nos. 1–5.
Form 1—Notice of Appeal, GSA Form 2465.
Form 2—Notice of Appearance.
Form 3—Subpoena, GSA Form 9534.
Form 4—Government Certificate of Finality.
Form 5—Appellant/Applicant Certificate of Finality.

Authority: 41 U.S.C. 601–613.

6101.0 Foreword.

(a) The General Services Administration Board of Contract Appeals was established under the Contract Disputes Act of 1978, 41 U.S.C. 601–613, as an independent tribunal to hear and decide contract disputes between government contractors and the General Services Administration (GSA) and other executive agencies of the United States.

(b) As an agency board established under the Contract Disputes Act, the Board is required to ''provide to the fullest extent practicable, informal, expeditious and inexpensive resolution of disputes.'' 41 U.S.C. 607(e). The rules in part 6101 represent the Board's concerted effort to be responsive to this charge in standard proceedings. In further response to this mandate, the Board also uses a variety of techniques intended to shorten and simplify, when appropriate, the proceedings normally used to resolve contract disputes. These techniques are described in part 6102.

(c) As indicated in part 6102, the Board fully supports the use of alternative dispute resolution (ADR) in all appropriate cases. To encourage the prompt, expert, and inexpensive resolution of contract disputes as promoted by the Federal Acquisition Streamlining Act of 1994, Public Law 103–355, 108 Stat. 3243, the Board will also make a Board Neutral available for an ADR proceeding, as described in 6102.4, either before or after the issuance of a decision by a contracting officer of any agency if a joint written request is submitted to the Office of the Clerk of the Board by the parties.

(d) The Board also conducts proceedings as required under other laws. In all matters before it, the Board will act in accordance with this part and Part 6102 and applicable standards of conduct so that the integrity, impartiality, and independence of the Board are preserved.

6101.1 Scope of rules; definitions; construction; rulings and orders; and panels; situs [Rule 101].

(a) *Scope.* The rules contained in this part and Part 6102 govern proceedings in all cases filed with the Board on or after October 7, 1996, and all further proceedings in cases then pending, except to the extent that, in the opinion of the Board, their use in a particular case pending on the effective date would be infeasible or would work an injustice, in which event the former procedure applies. The Board will look to the rules in this part and Part 6102 for guidance in conducting other proceedings authorized by law.

(b) *Definitions*—(1) *Appeal; appellant.* The term ''appeal'' means a contract dispute filed with the Board. The term ''appellant'' means as party filing an appeal.

(2) *Application; applicant.* The term ''application'' means a submission to the Board of a request for award of costs, under the Equal Access to Justice Act, 5 U.S.C. 504, pursuant to 6101.35. The term ''applicant'' means a party filing an application.

(3) *Board judge; judge.* The term ''Board judge'' or ''judge'' means a member of the Board.

(4) *Case.* The term ''case'' means an appeal, petition, or application.

(5) *Filing.* (i) Any document, other than a notice of appeal or an application for award of costs, is filed when it is received by the Office of the Clerk of the Board during the Board's working hours. A notice of appeal or an application for award of costs is filed upon the earlier of:

(A) Its receipt by the Office of the Clerk of the Board or

(B) If mailed, the date on which it is mailed. A United States Postal Service postmark shall be prima facie evidence that the document with which it is associated was mailed on the date thereof.

(ii) Facsimile transmissions to the Board and the parties are permitted. Parties are expected to submit their facsimile machine numbers with their filings. The Board's facsimile machine number is: (202) 501–0664. The filing of a document by facsimile transmission occurs upon receipt by the Board of the entire printed submission. Parties are specfically cautioned that deadlines for the filing of cases will not be extended merely because the Board's facsimile machine is busy or otherwise unavailable at the time on which the filing is due.

(6) *Party.* The term ''party'' means an appeallant, applicant, petitioner, or respondent.

(7) *Petition; petitioner.* The term ''petition'' means a request filed under 41 U.S.C. 605(c)(4) that the Board direct a contracting officer to issue a written decision on a claim. The term ''petitioner'' means a party submitting a petition.

(8) *Respondent.* The term ''respondent'' means the Government agency whose decision, action, or inaction is the subject of an appeal, petition, or appplication.

(9) *Working day.* The term ''working day'' means any date other than a Saturday, Sunday, or federal holiday.

(10) *Working hours.* The Board's working hours are 8:00 a.m. to 4:30 p.m., Eastern Time, on each working day.

(c) *Construction.* The rules in this part and part 6102 shall be construed to secure the just, speedy, and inexpensive resolution of every case. The Board looks to the Federal Rules of Civil Procedure for guidance in construing those Board rules which are similar to Federal Rules.

(d) *Rulings, orders, and directions.* The Board may apply the rules in this part and part 6102 and make such rulings and issue such orders and directions as are necessary to secure the just, speedy, and inexpensive resolution of every case before the Board. Any ruling, order, or direction that the Board may make or issue pursuant to the rules in this part and part 6102 may be made on the motion or request of any party or on the initiative of the Board. The Board may also amend, alter, or vacate a ruling, order, or direction upon such terms as are just. In making rulings and issuing orders and directions pursuant to the rules in this part and part 6102, the Board takes into consideration those Federal Rules of Civil Procedure which address matters not specifically covered in this part and part 6102.

(e) *Panels.* Each case will be assigned to a panel consisting of three judges, with one member designated as the panel chairman, in accordance with such procedures as may be established by the Board. The panel chairman is responsible for processing the case, including scheduling and conducting proceedings and hearings. In addition, the panel chairman may, without participation by other panel members, decide an appeal under the small claims procedure (6102.2), rule on nondispositive motions (except for amounts in controversy under 6102.2(a)(2)), and dismiss a case if no party objects (6101.28(c)). All other matters, except for those before the full Board under 6101.30, are decided for the Board by a majority of the panel.

(f) *Situs.* The address of the Office of the Clerk of the Board is: Room 7022, General Services Administration Building, 18th and F Streets, NW., Washington, DC 20405. The Clerk's telephone number is: (202) 501–0116. The Clerk's facsimile machine number is (702) 501–0664.

6101.2 Time: enlargement; computation [Rule 102].

(a) *Time for performing required actions.* All time limitations prescribed in the rules in this part and part 6102 or in any order or direction given by the Board are maximums, and the action required should be accomplished in less time whenever possible.

(b) *Enlarging time.* Upon request of a party for good cause shown, the Board may enlarge any time prescribed by the rules in this part and part 6102 or by an order or direction of the Board. The exception is the time limit for filing appeals (6101.5(b)(1)). A written request is required, but in exigent circumstances an oral request may be made and followed by a written request. An enlargement of time may be granted even through the request was filed after the time for taking the required action expired, but the party requesting the enlargement must show good cause for its inability to make the request before that time expired.

(c) *Computing time.* Except as otherwise required by law, in computing a period of time prescribed by the rules in this part and part 6102 or by order of the Board, the day from which the designated period of time begins to run shall not counted, but the last day of the period shall be counted unless that day is (1) a Saturday, a Sunday, or a federal holiday, or (2) a day on which the Office of the Clerk of the Board is required to close earlier than 4:30 p.m., or does not open at all, as in the case of inclement weather, in which event the period shall include the next working day. Except as otherwise provided in this paragraph, when the period of time prescribed or allowed is less than 11 days, any intervening Saturday, Sunday, or federal holiday shall not be counted. When the period of time prescribed or allowed is 11 days or more, intervening Saturdays, Sundays, and federal holidays shall be counted. Time for filing any document or copy thereof with the Board expires when the Office of the Clerk of the Board closes on the last day on which such filing may be made.

6101.3 Service of papers [Rule 103].

(a) *On whom and when service must be made.* When a party sends a document to the Board it must at the same time send a copy to the other party by mail or some other equally or more expeditious means of transmittal. Subpoenas (6101.20) and documents filed *in camera* (6101.12(h)) are exceptions to this requirement. Any papers required to be served on a party (except requests for discovery and responses thereto, unless ordered by the Board to be filed) shall be filed with the Board before service or within a reasonable time thereafter.

(b) *Proof of service.* Except when service is not required, a party sending a document to the Board must indicate to the Board that a copy has also been sent to the other party. This may be done by certificate of service, by the notation of a photostatic copy (cc:), or by any other means that can reasonably be expected to indicate to the Board that the other party has been provided a copy.

(c) *Failure to make service.* If a document sent to the Board by a party does not indicate that a copy has been served on the other party, the Board may return the document to the party that submitted it with such directions as it considers appropriate, or the Board may inquire whether a party has received a copy and note on the record the fact of inquiry and the response, and may also direct the party that submitted the document to serve a copy on the other party. In the absence of proof of service a document may be treated by the Board as not properly filed.

6101.4 Appeal file [Rule 104].

(a) *Submission to the Board by the contracting officer.* (1) Within 30 calendar days from receipt of notice that an appeal has been filed, or within such time as the Board may allow, the contracting officer shall file with the Board appeal file exhibits consisting of all documents and other tangible things relevant to the claim and to the contracting officer's decision which has been appealed, including:

(i) The contracting officer's decision, if any, from which the appeal is taken;

(ii) The contract, if any, including amendments, specifications, plans, and drawings;

(iii) All correspondence between the parties that is relevant to the appeal, including the written claim or claims that are the subject of the appeal, and evidence of their certification, if any;

(iv) Affidavits or statements of any witnesses on the matter in dispute and transcripts of any testimony taken before the filing of the notice of appeal;

(v) All documents and other tangible things on which the contracting officer relied in making the decision, and any correspondence relating thereto;

(vi) The abstract of bids, if relevant; and

(vii) Any additional existing evidence or information deemed necessary to determine the merits of the appeal.

(2) The contracting officer shall serve a copy of the appeal file on the appellant at the same time that the contracting officer files it with the Board, except that

(i) The contracting officer need not serve on the appellant those documents furnished the Board *in camera* pursuant to 6101.12(h), and

(ii) The contracting officer shall serve documents submitted under protective order only on those individuals who have been granted access to such documents by the Board. However, the contracting officer must serve on the appellant a list identifying the specific documents filed *in camera* or under protective order with the Board, giving sufficient details necessary for their recognition. This list must also be filed with the Board as an exhibit to the appeal file.

(b) *Submission to the Board by the appellant.* Within 30 calendar days after filing of the respondent's appeal file exhibits, or within such time as the Board may allow, the appellant shall file with the Board for inclusion in the appeal file documents or other tangible things relevant to the appeal that have not been submitted by the contracting officer. The appellant shall serve a copy of its additional exhibits upon the respondent at the same time as it files them with the Board.

(c) *Submissions on order of the Board.* The Board may, at any time during the pendency of the appeal, require any party to file other documents and tangible things as additional exhibits.

(d) *Organization of the appeal file.* Appeal file exhibits may be originals or true, legible, and complete copies. They shall be arranged in chronological order within each submission, earliest documents first; bound in a loose-leaf binder on the left margin except where size or shape makes such binding impracticable; numbered; tabbed; and indexed. The numbering shall be consecutive, in whole arabic numerals (no letters, decimals, or fractions), and continuous from one submission to the next, so that the complete file, after all submissions, will consist of one set of consecutively numbered exhibits. In addition, the pages within each exhibit shall be numbered consecutively unless the exhibit already is paginated in a logical manner. Consecutive pagination of the entire file is not required. The index should include the date and a brief description of each exhibit and shall indicate which exhibits, if any, have been filed with the Board *in camera* or under protective order or otherwise have not been served on every other party.

(e) *Lengthy or bulky materials.* The Board may waive the requirement to furnish other parties copies or duplicates of bulky, lengthy, or outsized

materials submitted to the Board as exhibits.

(f) *Use of appeal file as evidence.* All exhibits in the appeal file, except for those as to which an objection has been sustained, are part of the record upon which the Board will render its decision. Unless otherwise ordered by the Board, objection to any exhibit may be made at any time before the first witness is sworn or, if the appeal is submitted on the record pursuant to 6101.11, at any time prior to or concurrent with the first record submission. The Board may enlarge the time for such objections and will consider an objection made during a hearing if the ground for objection could not reasonably have been earlier known to the objecting party. If an objection is sustained, the Board will so note in the record.

(g) *When appeal file not required.* Upon motion of a party, the Board may postpone or dispense with the submission of any or all appeal file exhibits.

6101.5 Filing cases; time limits for filing; docketing [Rule 105].

(a) *Filing cases.* Filing of a case occurs as provided in 6101.1(b)(5).

(1) *Notice of appeal.* (i) A notice of appeal shall be in writing and should be signed by the appellant or by the appellant's attorney or authorized representative. If the appeal is from a contracting officer's decision, the notice of appeal should describe the decision in enough detail to enable the Board to differentiate that decision from any other; the appellant can satisfy this requirement by attaching to the notice of appeal a copy of the contracting officer's decision. If an appeal is taken from the failure of a contracting officer to issue a decision, the notice of appeal should describe in detail the claim that the contracting officer has failed to decide; the appellant can satisfy this requirement by attaching a copy of the written claim submission to the notice of appeal.

(ii) A written notice in any form, including the one specified in the appendix to this part and part 6102, is sufficient to initiate an appeal. The notice of appeal should include the following information:

(A) The number and date of the contract;

(B) The name of the agency and the component thereof against which the claim has been asserted;

(C) The name of the contracting officer whose decision or failure to decide is appealed and the date of the decision, if any;

(D) A brief account of the circumstances giving rise to the appeal; and

(E) An estimate of the amount of money in controversy, if any and if known.

(iii) The appellant must send a copy of the notice of appeal to the contracting officer whose decision is appealed or, if there has been no decision, to the contracting officer before whom the appellant's claim is pending.

(2) *Petition.* (i) A petition shall be in writing and signed by the petitioner or by the petitioner's attorney or authorized representative. The petition should describe in detail the claim that the contracting officer has failed to decide; the contractor can satisfy this requirement by attaching to the petition a copy of the written claim submission.

(ii) The petition should include the following information:

(A) The number and date of the contract;

(B) The name of the agency and the component thereof against which the claim has been asserted; and

(C) The name of the contracting officer whose decision is sought.

(3) *Application.* An application for costs shall meet all requirements specified in 6101.35(c).

(4) *Other participation.* The Board may, on motion, in its discretion, permit an entity to participate in a case in a special or limited way, such as by filing an *amicus curiae* brief.

(b) *Time limits for filing*—(1) *Appeals.* (i) An appeal from a decision of a contracting officer shall be filed no later than 90 calendar days after the date the appellant receives that decision.

(ii) An appeal may be filed with the Board should the contracting officer fail or refuse to issue a timely decision on a claim submitted in writing, properly certified if required.

(2) *Applications.* An application for costs shall be filed within 30 calendar days of a final disposition in the underlying appeal, as provided in 6101.35(b).

(c) *Notice of docketing.* Notices of appeal, petitions, and applications will be docketed by the Office of the Clerk of the Board, and a written notice of docketing will be sent promptly to all parties.

6101.6 Appearances; notice of appearance [Rule 106].

(a) *Appearances before the Board*—(1) *Appellant; petitioner; applicant.* Any appellant, petitioner, or applicant may appear before the Board by an attorney-at-law licensed to practice in a state, commonwealth, or territory of the United States, or in the District of Columbia. An individual appellant, petitioner, or applicant may appear in his own behalf; a corporation, trust, or association may appear by one of its officers or by any other authorized employee; and a partnership may appear by one of its members or by any other authorized employee.

(2) *Respondent.* The respondent may appear before the Board by an attorney-at-law licensed to practice in a state, commonwealth, or territory of the United States, or in the District of Columbia. Alternatively, if not prohibited by agency regulation or otherwise, the respondent may appear by the contracting officer or by the contracting officer's authorized representative.

(b) *Notice of appearance.* Unless a notice of appearance is filed by some other person, the person signing the notice of appeal, petition, or application shall be deemed to have appeared on behalf of the appellant, petitioner, or applicant, and the head of the respondent agency's litigation office shall be deemed to have appeared on behalf of the respondent. A notice of appearance in the form specified in the appendix to this part and Part 6102 is sufficient. Attorneys representing parties before the Board are required to list the state bars to which they are admitted and their state bar numbers or other bar identifiers.

(c) *Withdrawal of appearance.* Any person who has filed a notice of appearance and who wishes to withdraw from a case must file a motion which includes the name, address, telephone number, and facsimile machine number of the person who will assume responsibility for representation of the party in question. The motion shall state the grounds for withdrawal unless it is accompanied by a representation from the successor representative or existing co-counsel that the established case schedule will be met.

6101.7 Pleadings in appeals [Rule 107].

(a) *Pleadings required and permitted.* Except as the Board may otherwise order, the Board requires the submission of a complaint and an answer. In appropriate circumstances, the Board may order or permit a reply to an answer.

(b) *Complaint.* No later than 30 calendar days after the docketing of the appeal, the appellant shall file with the Board a complaint setting forth its claim or claims in simple, concise, and direct terms. The complaint should set forth the factual basis of the claim or claims, with appropriate reference to the contract provisions, and should state the amount in controversy, or an estimate

thereof, if any and if known. No particular form is prescribed for a complaint, and the Board may designate the notice of appeal, a claim submission, or any other document as the complaint, either on its own initiative or on request of the appellant, if such document sufficiently states the factual basis and amount of the claim.

(c) *Answer.* No later than 30 calendar days after the filing of the complaint or of the Board's designation of a complaint, the respondent shall file with the Board an answer setting forth simple, concise, and direct statements of its defenses to the claim or claims asserted in the complaint, as well as any affirmative defenses it chooses to assert. A dispositive motion or a motion for a more definite statement may be filed in lieu of the answer only with the permission of the Board. If no answer is timely filed, the board may enter a general denial, in which case the respondent may thereafter amend the answer to assert affirmative defenses only by leave of the Board and as otherwise prescribed by paragraph (f) of this section. The Board will inform the parties when it enters a general denial on behalf of the respondent.

(d) *Reply to an answer.* If the Board orders or permits a reply to an answer, it shall be filed as directed by the Board.

(e) *Modifications to requirement for pleadings.* If the appellant has elected the small claims procedure provided by 6102.2 or the accelerated procedure provided by 6102.3, the submission of pleadings shall be governed by the applicable section.

(f) *Amendment of pleadings.* Each party to an appeal may amend its pleadings once without leave of the Board at any time before a responsive pleading is filed; if the pleading is one to which no responsive pleading is permitted, such amendment may be made at any time within 20 calendar days after it is served or, in small claims proceedings under 6102.2, within 10 working days after it is served. The Board may permit the parties to amend pleadings further on conditions fair to both parties. If a response to the unamended pleading was required by the rules in this part or by an order of the Board, a response to the amended pleading shall be filed no later than 30 calendar days after the filing of the amended pleading or, in small claims proceedings, no later than 15 calendar days after the filing of the amended pleading. 6101.12(e) concerns amendments to pleadings to conform to the evidence.

6101.8 Motions [Rule 108].

(a) *How motions are made.* Motions may be oral or written. A written motion shall indicate the relief sought and, either in the text of the motion or in an accompanying legal memorandum, the grounds therefor. In addition, a motion for summary relief shall comply with the requirements of paragraph (g) of this section. 6101.25 prescribes the form and content of legal memoranda. Oral motions shall be made on the record and in the presence of the other party.

(b) *When motions may be made.* A motion filed in lieu of an answer pursuant to 6101.7(c) shall be filed no later than the date on which the answer is required to be filed or such later date as may be established by the Board. Any other dispositive motion shall be made as soon as practicable after the grounds therefor are known. Any other motion shall be made promptly or as required by this part.

(c) *Dispositive motions.* The following dispositive motions may properly be made before the Board:

(1) Motions to dismiss for lack of jurisdiction or for failure to state a claim upon which relief can be granted;

(2) Motions to dismiss for failure to prosecute;

(3) Motions for summary relief (analogous to summary judgment); and

(4) Any other motion to dismiss.

(d) *Other motions.* Other motions may be made in good faith and in proper form.

(e) *Jurisdictional questions.* The Board may at any time consider the issue of its jurisdiction to decide a case. When all facts touching upon the Board's jurisdiction are not to record, or in other appropriate circumstances, a decision on a jurisdictional question may be deferred pending a hearing on the merits or the filing of record submissions.

(f) *Procedure.* Unless otherwise directed by the Board, a party may respond to a written motion other than a motion pursuant to 6101.30, 6101.31, 6101.32, or 6101.33 at any time within 20 calendar days after the filing of the motion. Responses to motions pursuant to 6101.30, 6101.31, 6101.32, or 6101.33 may be made only as permitted or directed by the Board. The Board may permit hearing or oral argument on written motions and may require additional submissions from any of the parties.

(g) *Motions for summary relief.* (1) A motion for summary relief should be filed only when a party believes that, based upon uncontested material facts, it is entitled to relief in whole or in part as a matter of law. A motion for summary relief should be filed as soon as feasible, to allow the Board to rule on the motion in advance of a scheduled hearing date.

(2) With each motion for summary relief, there shall be served and filed a separate document titled Statement of Uncontested Facts, which shall contain in separately numbered paragraphs all of the material facts upon which the moving party bases its motion and as to which it contends there is no genuine issue. This statement shall include references to the supporting affidavits or declarations and documents, if any, and to the 6101.4 appeal file exhibits relied upon to support such statement.

(3) An opposing party shall file with its opposition (or cross-motion) a separate document titled Statement of Genuine Issues. This document shall identify, by reference to specific paragraph numbers in the moving party's Statement of Uncontested Facts, those facts as to which the opposing party claims there is a genuine issue necessary to be litigated. An opposing party shall state the precise nature of its disagreement and give its version of the facts. This statement shall include references to the supporting affidavits or declarations and documents, if any, and to the 6101.4 appeal file exhibits that demonstrate the existence of a genuine dispute. An opposing party may also file a Statement of Uncontested Facts as to any relevant matters not covered by the moving party's statement.

(4) When a motion for summary relief is made and supported as provided in this section, an opposing party may not rest upon the mere allegations or denials of its pleadings, but the opposing party's response, by affidavits or as otherwise provided by this section, must set forth specific facts showing that there is a genuine issue of material fact. If the opposing party does not so respond, summary relief, if appropriate, shall be entered against that party. For good cause shown, if an opposing party cannot present facts essential to justify its opposition, the Board may defer ruling on the motion to permit affidavits to be obtained or depositions to be taken or other discovery to be conducted, or may made such other order as is just.

(h) *Effect of pending motion.* Except as this part and part 6102 provide or the Board may order, a pending motion shall not excuse the parties from proceeding with the case in accordance with this part and part 6102 and the orders and directions of the Board.

6101.9 Election of hearing or record submission [Rule 109].

Each party shall inform the Board, in writing, whether it elects a hearing or submission of its case on the record

pursuant to 6101.11. Such an election may be filed at any time unless a time for filing is prescribed by the Board. A party electing to submit its case on the record pursuant to 6101.11 may also elect to appear at a hearing solely to cross-examine any witness presented by the opposing party, provided that the Board is informed of that party's intention within 10 working days of its receipt of notice of the election of hearing by the other party. If a hearing is elected, the election should state where and when the electing party desires the hearing to be held and should explain the reasons for its choices. A hearing will be held if either party elects one. If a party's decision whether to elect a hearing is dependent upon the intentions of the other party, it shall consult with the other party before filing its election. If there is to be a hearing, it will be held at a time and place prescribed by the Board after consultation with the party or parties electing the hearing. The record submissions from a party that has elected to submit its case on the record shall be due as provided in 6101.11.

6101.10 Conferences; conference memorandum; prehearing order; prehearing and presubmission briefs [Rule 110].

(a) *Conferences.* The Board may convene the parties in conference, either by telephone or in person, for any purpose. The conference may be stenographically or electronically recorded, at the discretion of the Board. Matters to be considered and actions to be taken at a conference may include:

(1) Simplifying, clarifying, or severing the issues;

(2) Stipulations, admissions, agreements, and rulings to govern the admissibility of evidence, understandings on matters already of record, or other similar means of avoiding unnecessary proof;

(3) Plans, schedules, and rulings to facilitate discovery;

(4) Limiting the number of witnesses and other means of avoiding cumulative evidence;

(5) Stipulations or agreements disposing of matters in dispute; or

(6) Ways to expedite disposition of the case or to facilitate settlement of the dispute, including, if the parties and the Board agree, the use of alternative dispute resolution techniques, as provided in 6102.1 and 6102.4.

(b) *Conference memorandum.* The Board may prepare a memorandum of the results of a conference or issue an order reflecting any actions taken, or both. A memorandum or order so issued shall be placed in the record of the case and sent to each party. Each party shall have 5 working days after receipt of a memorandum to object to the substance of it.

(c) *Prehearing order.* The Board may issue a prehearing or presubmission order to govern the proceedings in a case.

(d) *Prehearing or presubmission briefs.* A party may, by leave of the Board, file a prehearing or presubmission brief at any time before the hearing or upon or before the date on which first record submissions are due.

6101.11 Submission on the record without a hearing [Rule 111].

(a) *Submission on the record.* (1) A party may elect to submit its case on the record without a hearing. A party submitting its case on the record may include in its written record submission or submissions:

(i) Any relevant documents or other tangible things it wishes the Board to admit into evidence;

(ii) Affidavits, depositions, and other discovery materials that set forth relevant evidence; and

(iii) A brief or memorandum of law.

(2) The Board may require the submission of additional evidence or briefs and may order oral argument in a case submitted on the record.

(b) *Time for submission.* (1) If both parties have elected to submit the case on the record, the Board will issue an order prescribing the time for initial and, if appropriate, reply record submissions.

(2) If one party has elected a hearing and the other party has elected to submit its case on the record, the party submitting on the record shall make its initial submission no later than the commencement of the hearing or at an earlier date if the Board so orders, and a further submission in the form of a brief at the time for submission of posthearing briefs.

(c) *Objections to evidence.* Unless otherwise directed by the Board, objections to evidence (other than the appeal file and supplements thereto) in a record submission may be made within 10 working days after the filing of the submission. Replies to such objections, if any, may be made within 10 working days after the filing of the objection. The Board may rule on such objections in its opinion deciding the merits or otherwise disposing of the case.

6101.12 Record of Board proceedings [Rule 112].

(a) *Composition of the record for decision.* (1) The record upon which any decision of the Board will be rendered consists of:

(i) The notice of appeal, petition, or application;

(ii) Appeal file exhibits other than those as to which objection has been sustained;

(iii) Hearing exhibits other than those as to which an objection has been sustained;

(iv) Pleadings;

(v) Motions and responses thereto;

(vi) Memoranda, orders, rulings, and directions to the parties issued by the Board;

(vii) Documents and other tangible things admitted in evidence by the Board;

(viii) Written transcripts or electronic recordings of proceedings;

(ix) Stipulations and admissions by the parties;

(x) Depositions, or parts thereof, received in evidence;

(xi) Written interrogatories and responses received in evidence;

(xii) Briefs and memoranda of law; and

(xiii) Anything else that the Board may designate.

(2) All other papers and documents in a case are part of the administrative record of the proceedings. The administrative record shall include file and hearing exhibits offered but not received in evidence in a case; it may also include correspondence with and between the parties, and depositions, interrogatories, offers of proof contained in the transcript, and other documents that are not part of the record for decision.

(b) *Time for entry into the record.* Except as the Board may otherwise order, nothing other than posthearing briefs will be received into the record after a hearing is completed. In cases submitted on the record without a hearing, nothing will be received into the record after the time for filing of the last record submission. Briefs will be due as provided in 6101.25(b).

(c) *Closing of the record.* Except as the Board may otherwise order, no proof shall be received in evidence after a hearing is completed or, in cases submitted on the record without a hearing, after notice by the Board to the parties that the record is closed and that the case is ready for decision.

(d) *Notice that the case is ready for decision.* The Board will give written notice to the parties when the record is closed and the case is ready for decision.

(e) *Amendments to conform to the evidence.* When issues within the proper scope of a case, but not raised in the pleadings, have been raised without objection or with permission of the Board at a hearing (see 6101.21(h)) or in

record submissions, they shall be treated in all respects as if they had been raised in the pleadings. The Board may formally amend the pleadings to conform to the proof or may order that the record be deemed to contain pleadings so amended.

(f) *Enlargement of the record.* The Board may at any time require or permit enlargement of the record with additional evidence and briefs. It may reopen the record to receive additional evidence and oral argument at a hearing.

(g) *Inspection of the record of proceedings; release of any paper, document, or tangible thing prohibited.* Except for any part thereof that is subject to a protective order or deemed an *in camera* submission, the record of proceedings in a case shall be made available for inspection by any person. Such record shall be made available at the Office of the Clerk of the Board during the Board's normal working hours, as soon as practicable given the demands on the Board of processing the subject case and other cases. Except as provided in 6101.23(c) and 6101.37(d), no paper, document, or tangible thing which is part of the record of proceedings in a case may be released from the offices of the Board. Copies may be obtained by any person as provided in 6101.38(d). If such inspection or copying involves more than minimal costs to the Board, reimbursement will be required.

(h) *Protected and in camera submissions.* (1) A party may by motion request that the Board receive and hold materials under conditions that would limit access to them on the ground that such documents are privileged or confidential, or sensitive in some other way. The moving party must state the grounds for such limited access. The board may also determine on its own initiative to hold materials under such conditions. The manner in which such materials will be held, the persons who shall have access to them, and the conditions (if any) under which such access will be allowed will be specified in an order of the Board. If the materials are held under such an order, they will be part of the record of the case. If the Board denies the motion, the materials may be returned to the party that submitted them. If the moving party asks, however, that the materials be placed in the administrative record, *in camera*, for the purpose of possible later review of the Board's denial, the Board will comply with the request.

(2) A party may also ask, or the Board may direct, that testimony be received under protective order or *in camera.* The procedures under paragraph (h)(1) of this section shall be followed with respect to such request or direction.

6101.13 [Reserved].

6101.14 [Reserved].

6101.15 General provisions governing discovery [Rule 115].

(a) *Discovery methods.* The parties may obtain discovery by one or more of the following methods:

(1) Depositions upon oral examination or written questions;

(2) Written interrogatories;

(3) Requests for production of documents or other tangible things; and

(4) Requests for admission.

(b) *Scope of discovery.* Except as otherwise limited by order of the Board in accordance with this part and part 6102, the parties may obtain discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the pending case, whether it relates to the claim or defense of a party, including the existence, description, nature, custody, condition, and location of any books, documents, or other tangible things, and the identity and location of persons having knowledge of any discoverable matter. It is not a ground for objection that the information sought will be inadmissible if the information sought appears reasonably calculated to lead to the discovery of admissible evidence.

(c) *Discovery limits.* The Board may limit the frequency or extent of use of the discovery methods set forth in this section if it determines that:

(1) The discovery sought is unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive;

(2) The party seeking discovery has had ample opportunity by discovery in the case to obtain the information sought; or

(3) The discovery is unduly burdensome and expensive, taking into account the needs of the case, the amount in controversy, limitations on the parties' resources, and the importance of the issues at stake.

(d) *Conduct of discovery.* Parties may engage in discovery only to the extent the Board enters an order which either incorporates an agreed plan and schedule acceptable to the Board or otherwise permits such discovery as the moving party can demonstrate is required for the expeditious, fair, and reasonable resolution of the case.

(e) *Discovery conference.* Upon request of a party or on its own initiative, the Board may at any time hold an informal meeting or telephone conference with the parties to identify the issues for discovery purposes; establish a plan and schedule for discovery; set limitations on discovery, if any; and determine such other matters as are necessary for the proper management of discovery. The Board may include in the conference such other matters as it deems appropriate in accordance with 6101.10.

(f) *Discovery objections.* (1) In connection with any discovery procedure, the Board, on motion or on its own initiative, may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including, but not limited to, one or more of the following:

(i) That the discovery not be had;

(ii) That the discovery be had only on specified terms and conditions, including a designation of the time and place, or that the scope of discovery be limited to certain matters;

(iii) That the discovery be conducted with no one present except persons designated by the Board; and

(iv) That confidential information not be disclosed or that it be disclosed only in a designated way.

(2) Unless otherwise ordered by the Board, any objection to a discovery request must be filed within 15 calendar days after receipt. A party shall fully respond to any discovery request to which it does not file a timely objection. The parties are required to make a good faith effort to resolve objections to discovery requests informally.

(3) A party receiving an objection to a discovery request, or a party which believes that another party's response to a discovery request is incomplete or entirely absent, may file a motion to compel a response, but such a motion must include a representation that the moving party has tried in good faith, prior to filing the motion, to resolve the matter informally. The motion to compel shall include a copy of each discovery request at issue and the response, if any.

(g) *Failure to make or cooperate in discovery; sanctions.* If a party fails

(i) To appear for a deposition, after being served with a proper notice;

(ii) To serve answers or objections to interrogatories submitted under 6101.17, after proper service of interrogatories; or

(iii) To serve a written response to a request for inspection, production, and copying of any documents and things under 6101.17, the party seeking discovery may move the Board to impose appropriate sanctions under 6101.18.

(h) *Subpoenas.* A party may request the issuance of a subpoena in aid of

discovery under the provision of 6101.20.

6101.16 Depositions [Rule 116].

(a) *When depositions may be taken.* Upon request of a party, the Board may order the taking of testimony of any person by deposition upon oral examination or written questions before an officer authorized to administer oaths at the place of examination. Attendance of witnesses may be compelled by subpoena as provided in 6101.20, and the Board may upon motion order that the testimony at a deposition be recorded by other than stenographic means, in which event the order may designate the manner of recording, preserving, and filing the deposition and may include other provisions to ensure that the recorded testimony will be accurate and trustworthy. If the order is made, a party may, nevertheless, arrange to have a stenographic transcription made at its own expense.

(b) *Depositions: time; place; manner of taking.* The time, place, and manner of taking depositions, including the taking of depositions by telephone, shall be as agreed upon by the parties or, failing such agreement, as ordered by the Board. A deposition taken by telephone is taken at the place where the deponent is to answer questions.

(c) *Use of depositions.* At a hearing on the merits or upon a motion or interlocutory proceeding, any part or all of a deposition, so far as admissible and as though the witness were then present and testifying, may be used against a party who was present or represented at the taking of the deposition or who had reasonable notice thereof, in accordance with any of the following provisions:

(1) Any deposition may be used by a party for the purpose of contradicting or impeaching the testimony of the deponent as a witness.

(2) The deposition of a party or of anyone who at the time of taking the deposition was an officer, director, or managing agent, or a person designated to testify on behalf of a public or private corporation, partnership or association, or governmental agency which is a party may be used by an adverse party for any purpose.

(3) The deposition of a witness, whether or not a party, may be used by a party for any purpose in its own behalf if the Board finds that:

(i) The witness is dead;

(ii) The attendance of the witness at the place of hearing cannot be reasonably obtained, unless it appears that the absence of the witness was procured by the party offering the deposition;

(iii) The witness is unable to attend or testify because of illness, infirmity, age, or imprisonment;

(iv) The party offering the deposition has been unable to procure the attendance of the witness by subpoena; or

(v) Upon request and notice, exceptional circumstances exist which make it desirable in the interest of justice and with due regard to the importance of presenting the testimony of witnesses orally in open hearing, to allow the deposition to be used.

(4) If only part of a deposition is offered in evidence by a party, an adverse party may require the offering party to introduce any other part which in fairness ought to be considered with the part introduced.

(d) *Depositions pending appeal from a decision of the Board.*

(1) If an appeal has been taken from a decision of the Board, or before the taking of an appeal if the time therefor has not expired, the Board may allow the taking of depositions of witnesses to perpetuate their testimony for use in the event of further proceedings before the Board. In such case, the party that desires to perpetuate testimony may make a motion before the Board for leave to take the depositions as if the action were pending before the Board. The motion shall show:

(i) The names and addresses of the persons to be examined and the substance of the testimony which the moving party expects to elicit from each; and

(ii) The reasons for perpetuating the testimony of the persons named.

(2) If the Board finds that the perpetuation of testimony is proper to avoid a failure or a delay of justice, it may order the depositions to be taken and may make orders of the character provided for in 6101.15 and in this section. Thereupon, the depositions may be taken and used as prescribed in this part for depositions taken in actions pending before the Board. Upon request and for good cause shown, a judge may issue or obtain a subpoena, in accordance with 6101.20, for the purpose of perpetuating testimony by deposition during the pendency of an appeal from a Board decision.

6101.17 Interrogatories to parties; requests for admission; requests for production of documents [Rule 117].

Upon order from the Board permitting such discovery, a party may serve on another party written interrogatories, requests for admission, and requests for production of documents.

(a) *Written interrogatories.* Written interrogatories shall be answered separately in writing, signed under oath or accompanied by a declaration under penalty of perjury, and answered within 30 calender days after service. Objections shall be filed within the time limits set forth in 6101.15(f)(2). An interrogatory otherwise proper is not necessarily objectionable merely because an answer to the interrogatory may involve an opinion or contention that relates to fact or the application of law to fact, but the Board may order that such an interrogatory need not be answered until after designated discovery has been completed or until a conference has been held, or some other event has occurred.

(b) *Option to produce business records.* Where the answer to an interrogatory may be derived or ascertained from the business records of the party upon which the interrogatory has been served, or from an examination, audit, or inspection of such business records, including a compilation, abstract, or summary thereof, and the burden of deriving or ascertaining the answer is substantially the same for the party serving the interrogatory as for the party served, it is a sufficient answer to such interrogatory to specify the records from which the answer may be derived or ascertained and to afford to the party serving the interrogatory reasonable opportunity to examine, audit, or inspect such records and to make copies, compilations, abstracts, or summaries thereof. Such specification shall be in sufficient detail to permit the interrogating party to locate and to identify, as readily as can the party served, the records from which the answer may be ascertained.

(c) *Written requests for admission.* A written request for the admission of the truth of any matter, within the proper scope of discovery, that relates to statements or opinions of fact or of the application of law to fact, including the genuineness of any documents, is to be answered in writing and signed within 30 calendar days after service. Objections shall be filed within the time limits set forth in 6101.15(f)(2). Otherwise, the matter therein may be deemed to be admitted. Any matter admitted is conclusively established for the purpose of the pending action, unless the Board on motion permits withdrawal or amendment of the admission. Any admission made by a party under this paragraph is for the purpose of the pending action only and is not an admission for any other purpose, nor may it be used against the party in any other proceeding.

(d) *Written requests for production of documents.* A written request for the

production, inspection, and copying of any documents and things shall be answered within 30 calendar days after service. Objections shall be filed within the time limits set forth in 6101.15(f)(2).

(e) *Change in time for response.* Upon request of a party, or on its own initiative, the Board may prescribe a period of time other than that specified in this section.

(f) *Responses.* A party that has responded to written interrogatories, requests for admission, or requests for production of documents, upon becoming aware of deficiencies or inaccuracies in its original responses, or upon acquiring additional information or additional documents relevant thereto, shall, as quickly as practicable, and as often as necessary, supplement its responses to the requesting party with correct and sufficient additional information and such additional documents as are necessary to give a complete and accurate response to the request.

6101.18 Sanctions and other proceedings [Rule 118].

(a) *Standards.* All parties and their representatives, attorneys, and any expert/consultant retained by them or their attorneys, must obey directions and orders prescribed by the Board and adhere to standards of conduct applicable to such parties and persons. As to an attorney, the standards include the rules of professional conduct and ethics of the jurisdictions in which an attorney is licensed to practice, to the extent that those rules are relevant to conduct affecting the integrity of the Board, its process, and its proceedings. The Board will also look to voluntary professional guidelines in evaluating an individual's conduct.

(b) *Sanctions.* When a party or its representative or attorney or any expert/consultant fails to comply with any direction or order issued by the Board (including an order to provide or permit discovery), or engages in misconduct affecting the Board, its process, or its proceedings, the Board may make such orders as are just, including the imposition of appropriate sanctions. The sanctions include:

(1) Taking the facts pertaining to the matter in dispute to be established for the purpose of the case in accordance with the contention of the party submitting the discovery request;

(2) Forbidding challenge of the accuracy of any evidence;

(3) Refusing to allow the disobedient party to support or oppose designated claims or defenses;

(4) Prohibiting the disobedient party from introducing in evidence designated documents or items of testimony;

(5) Striking pleadings or parts thereof, or staying further proceedings until the order is obeyed;

(6) Dismissing the case or any part thereof;

(7) Enforcing the protective order and disciplining individuals subject to such other violation thereof, including disqualifying a party's representative, attorney, or expert/consultant from further participation in the case; or

(8) Imposing such other sanctions as the Board deems appropriate.

(c) *Denial of access to protected material for prior violations of protective orders.* The Board may in its discretion deny access to protected material to any person found to have previously violated the Board's protective order.

(d) *Disciplinary proceedings.*—(1) In addition to the other procedures in this section, the Board may discipline individual party representatives, attorneys, and experts/consultants for a violation of any Board order or direction or standard of conduct applicable to such individual where the violation seriously affects the integrity of the Board's process or proceedings. Sanctions may be public or private, and may include admonishment, disqualification from a particular matter, referral to an appropriate licensing authority, or such other action as circumstances may warrant.

(2) The Board in its discretion may suspend an individual from appearing before the Board as a party representative, attorney, or expert/consultant if, after affording such individual notice and an opportunity to be heard, a majority of the members of the full Board determines such a sanction is warranted.

6101.19 Hearings: scheduling; notice; unexcused absences [Rule 119].

(a) *Scheduling of hearings.* Hearings will be held at the time and place ordered by the Board and will be scheduled at the discretion of the Board. In scheduling hearings, the Board will consider the requirements of this part and part 6102, the need for orderly management of the Board's caseload, and the stated desires of the parties as expressed in their elections filed pursuant to 6101.9 or otherwise. The time or place for hearing may be changed by the Board at any time.

(b) *Notice of hearing.* Notice of hearing will be by written order of the Board. Notice of changes in the hearing schedule will also be by written order when practicable but may be oral in exigent circumstances. Except as the Board may otherwise order, each party that plans to attend the hearing shall, within 10 working days of receipt of:

(1) A written notice of hearing or

(2) Any notice of a change in hearing schedule stating that an acknowledgment is required, notify the Board in writing that it will attend the hearing.

(c) *Unexcused absence from hearing.* In the event of the unexcused absence of a party from a hearing, the hearing will proceed, and the absent party will be deemed to have elected to submit its case on the record pursuant to 6101.11.

6101.20 Subpoenas [Rule 120].

(a) *Voluntary cooperation in lieu of subpoena.* Each party is expected to:

(1) Cooperate by making available witnesses and evidence under its control, when requested by another party, without issuance of a subpoena; and

(2) Secure voluntary attendance of third-party witnesses and production of evidence by third parties, and when practicable, without issuance of a subpoena.

(b) *General.* Upon the written request of any party filed with the Office of the Clerk of the Board, or on the initiative of a judge, a subpoena may be issued that commands the person to whom it is directed to:

(1) Attend and give testimony at a deposition in a city or county where that person resides or is employed or transacts business in person, or at another location convenient to that person that is specifically determined by the Board;

(2) Attend and give testimony at a hearing; and

(3) Produce the books, papers, documents, and other tangible things designated in the subpoena.

(c) *Request for subpoena.* A request for a subpoena shall state the reasonable scope and general relevance to the case of the testimony and of any documentary evidence sought. A request for a subpoena shall be filed at least 15 calendar days before the testimony of a witness or documentary evidence is to be provided. The Board may, in its discretion, honor requests for subpoenas not made within this time limitation.

(d) *Form; issuance.* Every subpoena shall be in the form specified in the appendix to this part and part 6102. Unless a party has the approval of a judge to submit a subpoena in blank (in whole or in part), a party shall submit to the judge a completed subpoena (save the ''Return on Service'' portion). In issuing a subpoena to a requesting party,

the judge shall sign the subpoena. The party to whom the subpoena is issued shall complete the subpoena before service.

(2) If the person subpoenaed is located in a foreign country, a letter rotatory or a subpoena may be issued and served under the circumstances and in the manner provided in 28 U.S.C. 1781–1784.

(e) *Service.* (1) The party requesting a subpoena shall arrange for service. Service shall be made as soon as practicable after the subpoena has been issued.

(2) A subpoena requiring the attendance of a witness at a deposition or hearing may be served at any place. A subpoena may be served by a United States marshal or deputy marshal, or by any other person who is not a party and not less than 18 years of age. Service of a subpoena upon a person named therein shall be made by personal delivery of a copy to that person and tender of the fees for one day's attendance and the mileage allowed by 28 U.S.C. 1821 or other applicable law; however, where the subpoena is issued on behalf of the Government, money payments need not be tendered in advance of attendance.

(f) *Proof of service.* The person serving the subpoena shall make proof of service thereof to the Board promptly and in any event before the date on which the person served must respond to the subpoena. Proof of service shall be made by completion and execution and submission to the Board of the ''Return on Service'' portion of a duplicate copy of the subpoena issued by a judge. If service is made by a person other than a United States marshal or his deputy, that person shall make an affidavit as proof by executing the ''Return on Service'' in the presence of a notary.

(g) *Motion to quash or to modify.* Upon written motion by the person subpoenaed or by a party, made within 14 calendar days after service, but in any event not later than the time specified in the subpoena for compliance, the Board may

(1) Quash or modify the subpoena if it is unreasonable and oppressive or for other good cause shown, or

(2) Require the party in whose behalf the subpoena was issued to advance the reasonable cost of producing subpoenaed documentary evidence. Where circumstances require, the Board may act upon such a motion at any time after a copy has been served upon opposing parties.

(h) *Contumacy or refusal to obey a subpoena.* In a case of contumacy or refusal to obey a subpoena by a person who resides, is found, or transacts business within the jurisdiction of a United States district court, the Board shall apply to the court through the Attorney General of the United States for an order requiring the person to appear before the board to give testimony, produce evidence or both. If a person fails to obey such an order, the court may punish that person for contempt of court.

6101.21 Hearing procedures [Rule 121].

(a) *Nature and conduct of hearings.* Except when necessary to maintain the confidentiality of protected material or testimony, or material submitted *in camera,* all hearings on the merits of cases shall be open to the public and conducted insofar as is convenient in regular hearing rooms. All other acts or proceedings may be done or conducted by the Board either in its offices or at other places.

(b) *Continuances; change of location.* Whenever practicable, a hearing will be conducted in one continuous session or a series of consecutive sessions at a single location. However, the Board may at any time continue the hearing to a future date and may arrange to conduct the hearing in more than one location. The Board may also continue a hearing to permit a party to conduct additional discovery on conditions established by the Board. In exercising its discretion to continue a hearing or to change its location, the Board will give due consideration to the same elements (set forth in 6101.19(a)) that it considers in scheduling hearings.

(c) *Availability of witnesses, documents, and other tangible things.* It is the responsibility of a party desiring to call any witness, or to use any document or other tangible thing as an exhibit in the course of a hearing, to ensure that whoever it wishes to call and whatever it wishes to use is available at the hearing.

(d) *Enlargement of the record.* The Board may at any time during the conduct of a hearing require evidence or argument in addition to that put forth by the parties.

(e) *Examination of witnesses.* Witnesses before the Board will testify under oath or affirmation. A party or the Board may obtain an answer from any witness to any question that is not the subject of an objection that the Board sustains.

(f) *Refusal to be sworn.* If a person called as a witness refuses to be sworn or to affirm before testifying, the Board may direct that witness to do so and, in the event of continued refusal, the Board may permit the taking of testimony without oath or affirmation. Alternatively, the Board may refuse to permit the examination of that witness, in which event it may state for the record the inferences it draws from the witness's refusal to testify under oath or affirmation. Alternatively, the Board may issue a subpoena to compel that witness to testify under oath or affirmation, and in the event of the witness's continued refusal to swear or affirm, may seek enforcement of that subpoena pursuant to 6101.20(h).

(g) *Refusal to answer.* If a witness refuses to answer a question put to him in the course of his testimony, the Board may direct that witness to answer and, in the event of continued refusal, the Board may state for the record the inferences if draws from the refusal to answer. Alternatively, the Board may issue a subpoena to compel that witness to testify and, in the event of the witness's continued refusal to testify, may seek enforcement of that subpoena pursuant to 6101.20(h).

(h) *Issues not raised by pleadings.* If evidence is objected to at a hearing on the ground that it is not within the issues raised by the pleadings, it may nevertheless be admitted by the Board if it is within the proper scope of the case. If such evidence is admitted, the Board may grant the objecting party a continuance to enable it to meet such evidence. If such evidence is admitted, the pleadings may be amended to conform to the evidence, as provided by 6101.12(e).

(i) *Delay by parties.* If the Board determines that the hearing is being unreasonably delayed by the failure of a party to produce evidence, or by the undue prolongation of the presentation of evidence, it may, by written order or by ruling from the bench, prescribe a time or times within which the presentation of evidence must be concluded, establish time limits on the direct or cross-examination of witnesses, and enforce such order or ruling by appropriate sanctions.

6101.22 Admissibility and weight of evidence [Rule 122].

(a) *Admissibility.* Any relevant evidence may be received. The Board may exclude relevant evidence to avoid unfair prejudice, confusion of the issues, undue delay, waste of time, or needless presentation of cumulative evidence. Hearsay evidence is admissible unless the Board finds it unreliable or untrustworthy.

(b) *Federal Rules of Evidence.* As a general matter, and subject to the other provisions of this section, the Board will base its evidentiary rulings on the Federal Rules of Evidence.

(c) *Weight and credibility.* The Board will determine the weight to be given to evidence and the credibility to be accorded witnesses.

(d) *Submission of evidence in camera.* 6101.12(h) governs submissions *in camera.*

6101.23 Exhibits [Rule 123].

(a) *Marking of exhibits.* (1) Documents and other tangible things offered in evidence by a party will be marked for identification by the Board during the hearing or, if it is convenient for the Board and the parties, before the commencement of the hearing. They will be numbered consecutively as the exhibits of the party offering them.

(2) If a party elects to proceed on the record without a hearing pursuant to 6101.11, documentary evidence submitted by that party will be numbered consecutively by the Board as appeal file exhibits.

(b) *Copies as exhibits.* Except upon objection sustained by the Board for good cause shown, copies of documents may be offered and received into evidence as exhibits, provided they are of equal legibility and quality as the originals, and such copies shall have the same force and effect as if they were the originals. If the Board so directs, a party offering a copy of a document as an exhibit shall have the original available at the hearing for examination by the Board and any other party. When the original of a document has been received into evidence as an exhibit, an accurate copy thereof may be substituted in evidence for the original by leave of the Board at any time.

(c) *Withdrawal of documentary exhibits and other papers.* With the permission of the Board, a party may remove an exhibit during the course of a proceeding. Otherwise, except as provided in 6101.37(d), no withdrawal of any papers in the Board's file is permitted. Inspection of the file at the Board's offices is permitted by 6101.12(g).

(d) *Disposition of physical exhibits.* Any physical (as opposed to documentary) exhibit may be disposed of by the Board at any time more than 90 calendar days after the expiration of the period for appeal from the decision of the Board, unless it has been earlier withdrawn by the party that submitted it.

6101.24 Transcripts of proceedings; corrections [Rule 124].

(a) *Transcripts* Except as the Board may otherwise order, all hearings, other than those under the small claims procedure prescribed by 6102.2, will be stenographically or electronically recorded and transcribed. Any other hearing or conference will be recorded or transcribed only by order of the Board. Copies or transcriptions of stenographic or electronic recordings not ordered to be transcribed by the Board will be furnished to the parties or other persons only on conditions prescribed by the Board, which may include the payment of the costs of copying or transcription. Each party is responsible for obtaining its own copy of the transcript if one is prepared.

(b) *Corrections* Corrections to an official transcript will be made only when they involve errors affecting its substance. The Board may order such corrections on motion or on its own initiative, and only after notice to the parties giving them opportunity to object. Such corrections will ordinarily be made either by hand with pen and ink or by the appending of an errata sheet, but when no other method of correction is practicable the Board may require the reporter to provide substitute or additional pages.

6101.25 Briefs and memoranda of law [Rule 125].

(a) *Form and content of briefs and memoranda of law.* Briefs and memoranda of law shall be typewritten on standard size 8½ by 11–inch paper. Otherwise, no particular form or organization is prescribed. Posthearing briefs should, at a minimum, succinctly set forth

(1) The facts of the case with citations to those places in the record where supporting evidence can be found and

(2) Argument with citations to supporting legal authorities. Memoranda of law should generally adhere as closely as practicable to the form and content of briefs.

(b) *Submission of posthearing briefs.* Except as the Board may otherwise order, posthearing briefs shall be filed 30 calendar days after the Board's receipt of the transcript; reply briefs, if filed, shall be filed 15 calendar days after the parties' receipt of the initial posthearing briefs. The Board will notify the parties of the date of its receipt of the transcript. In the event one party has elected a hearing and the other party has elected to submit its case on the record pursuant to 6101.11, the filing of record submissions in the form of briefs shall be governed by this section.

6101.26 Consolidation; separate hearings; separate determination of liability [Rule 126].

(a) *Consolidation.* When cases involving common questions of law or fact are pending, the Board may:

(1) Order a joint hearing of any or all of the matters at issue in the cases;

(2) Order the cases consolidated; or

(3) Make such other orders concerning the proceedings therein as are intended to avoid unnecessary costs or delay.

(b) *Separate hearings.* The Board may order a separate hearing of any case or cases or of any claims or issues or number of claims or issues therein. The Board may enter appropriate orders or decisions with respect to any claims or issues that are heard separately.

(c) *Separate determinations of liability.* The Board may:

(1) Limit a hearing to those issues of law and fact relating to the right of a party to recover, reserving the determination of the amount of recovery, if any, for other proceedings; and

(2) In its decision of an appeal, irrespective of whether there is evidence in the record concerning the amount of recovery, and whether or not a stipulation or order has been made, reserve determination of the amount of recovery for other proceedings. In any instance in which the Board has reserved its determination of the amount of recovery for other proceedings, its decision on the question of the right to recover shall be final, subject to the provisions of 6101.30 through 6101.33.

6101.27 Stay or suspension of proceedings; dismissals in lieu of stay or suspension [Rule 127].

(a) *Stay of proceedings to obtain contracting officer's decision.* The Board may in its discretion stay proceedings to permit a contracting officer to issue a decision when an appeal has been taken from the contracting officer's alleged failure to render a timely decision.

(b) *Suspension for other cause.* The Board may suspend proceedings in a case for good cause. The order suspending proceedings will prescribe the duration of the suspension or the conditions on which it will expire. The order may also prescribe actions to be taken by the parties during the period of suspension or following its expiration.

(c) *Dismissal in lieu of stay or suspension.* When circumstances beyond the control of the Board prevent the continuation of proceedings in a case, the Board may, in lieu of issuing an order suspending proceedings, dismiss the case without prejudice to reinstatement. Such a dismissal may require reinstatement by a date certain or within a certain period of time after the occurrence of a specified event. If the order of dismissal does not otherwise provide, it will be subject to the provisions of 6101.28(b).

6101.28 Dismissals [Rule 128].

(a) *Generally.* A case may be dismissed by the Board on motion of either party. A case may also be dismissed for reasons cited by the Board in a show cause order to which response has been permitted. Every dismissal shall be with prejudice to reinstatement of the case unless a dismissal without prejudice has been requested by a party or specified in a show cause order.

(b) *Dismissal without prejudice.* When a case has been dismissed without prejudice to its reinstatement and neither party has requested, within the period of time specified in this paragraph, that the case be reinstated, the case shall be deemed to have been dismissed with prejudice as of the expiration of 180 calendar days from the date of dismissal, or such other period as the Board may prescribe.

(c) *Issuance of order.* An order of dismissal shall be issued by the panel of judges to which the case has been assigned if the motion is contested or if the Board is acting consequent to its own show cause order. An order of dismissal may be issued by the panel chairman alone if the motion to dismiss is not contested.

6101.29 Decisions: format; procedure [Rule 129].

Except as provided in 6102.2 (small claims procedure), decisions of the Board will be made in writing upon the record as prescribed in 6101.12. Each of the parties will be furnished a copy of the decision certified by the Office of the Clerk of the Board, and the date of the receipt thereof by each party will be established in the record.

6101.30 Full Board consideration [Rule 130].

(a) *Requests.* (1) A request for full Board consideration is not favored. Ordinarily, full Board consideration will be ordered only when

(i) It is necessary to secure or maintain uniformity of Board decisions, or

(ii) The matter to be referred is one of exceptional importance.

(2) A request for full Board consideration may be made by either party on any date which is both

(i) After the panel to which the case is assigned has issued its decision on a motion for reconsideration or relief from decision and

(ii) Within 10 working days after the date on which that party receives that decision. Any party making a request for full Board consideration shall state concisely in the motion the precise grounds on which the request is based.

(3) The full Board on its own may initiate consideration of a matter

(i) At any time while the case is before the Board,

(ii) No later than the last date on which any party may file a motion for reconsideration or relief from decision or order, or

(iii) If such a motion is filed by a party, within ten days after a panel has resolved it.

(b) *Consideration.* Promptly after such a request is made, a ballot will be taken among the judges; if a majority of them favors the request, the request will be granted. The result of the vote will promptly be reported by the Board through an order. The concurring or dissenting view of any judge who wishes to express such a view may issue at the time of such order or at any time thereafter.

(c) *Decisions.* If full Board consideration is granted, a vote shall be taken promptly on the pending matter. After this vote is taken, the Board shall promptly, by order, issue its determination, which shall include the concurring or dissenting view of any judge who wishes to express such a view.

6101.31 Clerical mistakes [Rule 131].

Clerical mistakes in decisions, orders, or other parts of the record, and errors arising therein through oversight or inadvertence, may be corrected by the Board at any time on its own initiative or upon motion of a party on such terms, if any, as the Board may prescribe. During the pendency of an appeal to another tribunal, such mistakes may be corrected only with leave of the appellate tribunal.

6101.32 Reconsideration; amendment of decisions; new hearings [Rule 132].

(a) *Grounds.* Reconsideration may be granted, a decision or order may be altered or amended, or a new hearing may be granted, for any of the reasons stated in 6101.33(a) and the reasons established by the rules of common law or equity applicable as between private parties in the courts of the United States. Reconsideration, or a new hearing, may be granted on all or any of the issues. Arguments already made and reinterpretations of old evidence are not sufficient grounds for granting reconsideration. On granting a motion for a new hearing, the Board may open the decision if one has been issued, take additional testimony, amend findings of fact and conclusions of law, or make new findings and conclusions and direct the entry of a new decision.

(b) *Procedure.* (1) Any motion under this section shall comply with the provisions of 6101.8 and shall set forth:

(i) The reason or reasons why the Board should consider the motion; and

(ii) The relief sought and the grounds therefor.

(2) If the Board concludes that the reasons asserted for its consideration of the motion are insufficient, it may deny the motion without considering the relief sought and the grounds asserted therefor. If the Board grants the motion, it will issue an appropriate order which may include directions to the parties for further proceedings.

(c) *Time for filing.* A motion for reconsideration, to alter or amend a decision or order, or for a new hearing shall be filed in an appeal or petition within 30 calendar days and in an application within 7 working days after the date of receipt by the moving party of the decision or order. Not later than 30 calendar days after issuance of a decision or order, the Board may, on its own initiative, order reconsideration or a new hearing or alter or amend a decision or order for any reason that would justify such action on motion of a party.

(d) *Effect of motion.* A motion pending under this section does not affect the finality of a decision or suspend its operation.

6101.33 Relief from decision or order [Rule 133].

(a) *Grounds.* The Board may relieve a party from the operation of a final decision or order for any of the following reasons:

(1) Newly discovered evidence which could not have been earlier discovered, even through due diligence;

(2) Justifiable or excusable mistake, inadvertence, surprise, or neglect;

(3) Fraud, misrepresentation, or other misconduct of an adverse party;

(4) The decision has been satisfied, released, or discharged, or a prior decision upon which it is based has been reversed or otherwise vacated, and it is no longer equitable that the decision should have prospective application;

(5) The decision is void, whether for lack of jurisdiction or otherwise; or

(6) Any other ground justifying relief from the operation of the decision or order.

(b) *Procedure.* Any motion under this section shall comply with the provisions of 6101.8 and 6101.32(b), and will be considered and ruled upon by the Board as provided in 6101.32.

(c) *Time for filing.* Any motion under this section shall be filed as soon as practicable after the discovery of the reasons therefor, but in any event no later than 120 calendar days or, in appeals under the small claims

procedure of 6102.2, no later than 30 calendar days after the date of the moving party's receipt of the decision or order from which relief is sought. In considering the timeliness of a motion filed under this section, the Board may consider when the grounds therefor should reasonably have been known to the moving party.

(d) *Effect of motion.* A motion pending under this section does not affect the finality of a decision or suspend its operation.

6101.34 Harmless error [Rule 134].

No error in the admission or exclusion of evidence, and no error or defect in any ruling, order, or decision of the Board, and no other error in anything done or omitted to be done by the Board will be a ground for granting a new hearing or for vacating, reconsidering, modifying, or otherwise disturbing a decision or order of the Board unless refusal to act upon such error will prejudice a party or work a substantial injustice. At every stage of the proceedings the Board will disregard any error or defect that does not affect the substantial rights of the parties.

6101.35 Award of costs [Rule 135].

(a) *Applications for costs.* An appropriate party in a proceeding before the Board may apply for an award of costs, including if applicable an award of attorney fees, under the Equal Access to Justice Act, 5 U.S.C. 504, or any other provision that may entitle that party to such an award, subsequent to the Board's decision in the proceeding. For purposes of this section, ''decision'' includes orders of dismissal resulting from settlement agreements that bring to an end the proceedings before the Board.

(b) *Time for filing.* A party seeking an award may submit an application no later than 30 calendar days after a final disposition in the underlying appeal. In the case of an appeal that is adjudicated, the Board's decision becomes final (for purposes of this section) when it is not appealed to the United States Court of Appeals for the Federal Circuit within the time permitted for appeal or, if the decision is appealed, when the time for petitioning the Supreme Court for certiorari has expired. In the case of an appeal that is resolved as a result of settlement, the Board's disposition becomes final (for purposes of this section) after receipt by the applicant of the order granting or dismissing the appeal.

(c) *Application requirements.* An application for costs shall:

(1) Identify the applicant and the appeal for which costs are sought, and the amount being sought;

(2) Establish that all applicable prerequisites for an award have been satisfied, including a succinct statement of why the applicant is eligible for an award of costs;

(3) Be accompanied by an exhibit fully documenting any fees or expenses being sought, including the cost of any study, analysis, engineering report, test, project, or similar matter. The date and a description of all services rendered or costs incurred shall be submitted for each profession firm or individual whose services are covered by the application, showing the hours spent in connection with the proceeding by each individual, a description of the particular services performed by specific date, the rate at which each fee has been computed, any expenses for which reimbursement is sought, and the total amount paid or payable by the applicant on account of the sought-after costs. Except in exceptional circumstances, all exhibits supporting applications for fees or expenses sought shall be publicly available. The Board may require the applicant to provide vouchers, receipts, or other substantiation for any costs claimed and/or to submit to an audit by the Government of the claimed costs;

(4) Be signed by the applicant or an authorized officer, employee, or attorney of the applicant;

(5) Contain or be accompanied by a written verification under oath or affirmation, or declaration under penalty of perjury, that the information provided in the application is true and correct;

(6) If the applicant asserts that it is a qualifying small business concern, contain evidence thereof; and

(7) If the application requests reimbursement of attorney fees that exceed the statutory rate, explain why an increase in the cost of living or a special factor, such as the limited availability of qualified attorneys for the proceedings involved, justifies such fees.

(d) *Proceedings.* (1) Within 30 calendar days after receipt by the respondent of an application under this section, the respondent may file an answer. The answer shall explain in detail any objects to the award requested and set out the legal and factual bases supporting the respondent's position. If the respondent contends that any fees for consultants or expert witnesses for which reimbursement is sought in the application exceed the highest rate of compensation for expert witnesses paid by the agency, the respondent shall include in the answer evidence of such highest rate.

(2) Further proceedings shall be held only by order of the Board and only when necessary for full and fair resolution of the issues arising from the application. Such proceedings shall be minimized to the extent possible and shall not include relitigation of the case on the merits. A request that the Board order further proceedings under this section shall describe the disputed issues and explain why additional proceedings are necessary to resolve those issues.

(e) *Decision.* Any award ordered by the Board shall be paid pursuant to 6101.36.

6101.36 Payment of Board awards [Rule 136].

(a) *Generally.* When permitted by law, payment of Board awards may be made in accordance with 31 U.S.C. 1304. Awards by the Board pursuant to the Equal Access to Justice Act shall be directly payable by the respondent agency over which the applicant has prevailed in the underlying appeal.

(b) *Conditions for payment.* Before a party may obtain payment of a Board award pursuant to 31 U.S.C. 1304, one of the following must occur:

(1) Both parties must, by execution of a Certificate of Finality, waive their rights to relief under 6101.32 and 6101.33 and also their rights to appeal the decision of the Board; or

(2) The time for filing an appeal must expire.

(c) *Procedure for filing of certificates of finality.* Whenever the Board issues a decision or an order awarding a party any amount of money, it will attach to the copy of the decision sent to each party forms such as those illustrated in the appendix to this part and part 6102. The conditions for payment prescribed in paragraph (b)(1) of this section are satisfied if each of the parties returns a completed and duly executed copy of this form to the Board. When the form is executed on behalf of an appellant or applicant by an attorney or other representative, proof of signatory authority shall also be furnished. Upon receipt of completed and duly executed Certificates of Finality from the parties, the Board will forward a copy of each such certificate (together with proof of signatory authority, if required) and a certified copy of its decision to the

United States Department of the Treasury to be certified for payment.

(d) *Procedure in absence of certificate of finality.* When one or both of the parties fails to submit a duly executed Certificate of Finality, but the conditions for payment have been satisfied as provided in paragraph (b)(2) of this section, the appellant or applicant may file a written request that the Board forward its decision to the United States Department of the Treasury for payment. Thereupon, the Board will forward a copy of that request and a certified copy of its decision to the United States Department of the Treasury to be certified for payment.

(e) *Stipulated award.* When an appeal is settled, the parties may file with the Board a stipulation setting forth the amount of the award and stating

(1) That they will not seek reconsideration of, or relief from, the Board's decision, and

(2) That they will not appeal the decision. The Board will adopt the parties' stipulation by decision. The Board's decision under this paragraph is an adjudication of the case on the merits.

6101.37 Record on review of a Board decision [Rule 137].

(a) *Record on review.* When a party has appealed a Board decision to the United States Court of Appeals for the Federal Circuit, the record on review shall consist of the decision sought to be reviewed, the record before the Board as described in 6101.12, and such other material as may be required by the Court of Appeals.

(b) *Notice.* At the same time a party seeking review of a Board decision files a notice of appeal, that party shall provide a copy of the notice to the Board.

(c) *Filing of certified list of record materials.* Promptly after service upon the Board of a copy of the notice of appeal of a Board decision, the Office of the Clerk of the Board shall file with the Clerk of the United States Court of Appeals for the Federal Circuit a certified list of all documents, transcripts of testimony, exhibits, and other materials constituting the record, or a list of such parts thereof as the parties may designate, adequately describing each. The Board will retain the record and transmit any part thereof to the Court upon the Court's order during the pendency of the appeal.

(d) *Request by attorney of record to review record.* When a case is on appeal, an attorney of record may request permission from the Board to sign out the record on appeal to review and copy, for a reasonable period of time, if the attorney is unable to gain access to the record from another source.

6101.38 Office of the Clerk of the Board [Rule 138].

(a) *Open for the filing of papers.* The Office of the Clerk of the Board shall receive all papers submitted for filing, and shall be open for this purpose from 8:00 a.m. to 4:30 p.m., Eastern Time, on each day that is not a Saturday, Sunday, federal holiday, a day on which the Office is required to close earlier than 4:30 p.m., or a day on which the Office does not open at all, as in the case of inclement weather.

(b) *Decisions and orders.* The Office of the Clerk shall keep in such form and manner as the Board may prescribe a correct copy of each decision or order of the Board subject to review and any other order or decision which the Board may direct to be kept.

(c) *Docket.* The Office of the Clerk shall keep a docket on which shall be entered the title and nature of all cases brought before the Board, the names of the persons filing such cases, the names of the attorneys or other persons appearing for the parties, and a record of all proceedings.

(d) *Copies and certification of papers.* Upon the request of any person, copies of papers and documents in a case may be provided by the Office of the Clerk. If making such copies involves more than minimal costs to the Board, reimbursement will be required. When required, the Office of the Clerk will certify copies of papers and documents as a true record of the Board. Except as provided in 6101.23(c) and 6101.37(d), the Office of the Clerk will not release original records in its possession to any person.

6101.39 Seal of the Board [Rule 139].

The Seal of the Board shall be a circular boss, the center portion of which shall depict the Seal of the General Services Administration. The outer margin of the seal shall bear the legend ''Board of Contract Appeals.'' The Seal shall be the means of authentication of all records, notices, orders, dismissals, opinions, subpoenas, and certificates issued by the Board.

6101.40 Forms [Rule 140].

The forms contained in the appendix to this part and part 6102 are sufficient under these parts and are intended to indicate the simplicity and brevity of statement which the rules in those parts contemplate. The subpoena form is a required form, and it may not be altered.

Appendix to Part 6101—Form Nos. 1–5

Form 1—Notice of Appeal, GSA Form 2465
Form 2—Notice of Appearance
Form 3—Subpoena, GSA Form 9534
Form 4—Government Certificate of Finality
Form 5—Appellant/Applicant Certificate of Finality

BILLING CODE 6829–AL–M

NOTICE OF APPEAL	DATE	OMB APPROVAL NO. 3090-0221

TO: Board of Contract Appeals
General Services Administration
Washington, DC 20405

I/We hereby appeal the final decision of _____ (Name of Contracting Officer), issued _____ (Date),

in connection with a dispute under Contract No. _____. This contract was awarded _____ (Date)

for _____ (Type of commodity, service, or construction)

by _____ (Name of agency and organizational unit), _____ (City and State)

1. DESCRIBE THE NATURE OF THE DISPUTE INVOLVED IN THE FINAL DECISION AND ANY OTHER CIRCUMSTANCES GIVING RISE TO THIS APPEAL:

2. DESCRIBE THE RELIEF WHICH YOU SEEK INCLUDING AN ESTIMATE OF THE AMOUNT OF MONEY IN CONTROVERSY, IF ANY, AND IF KNOWN:

APPELLANT			ATTORNEY FOR APPELLANT		
NAME			NAME		
TITLE			FIRM		
STREET			STREET		
CITY			CITY		
STATE	ZIP CODE	TELEPHONE NUMBER ( )	STATE	ZIP CODE	TELEPHONE NUMBER ( )
APPELLANT'S SIGNATURE			ATTORNEY'S SIGNATURE		

GENERAL SERVICES ADMINISTRATION GSA FORM 2465 (REV. 6-85)

Board of Contract Appeals

General Services Administration
Washington, D.C. 20405

Form 2

_____	:	
_____	:	GSBCA _____
_____	:	
Contract/Solicitation No.	:	
_____	:	

NOTICE OF APPEARANCE

To: _____
Board Judge
Board of Contract Appeals

Please enter my appearance as counsel for / representative of

_____ in the above captioned case.

_____	_____
(Name)	Date
_____	_____
(Title)	(Phone)
_____	_____
(Address)	(Facsimile)

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Notice of Appearance was mailed postage paid/delivered

this _____ day of _____, 19___, to _____.

_____
Signature

Note: This format shall not be printed, reproduced, or stocked by the Central Office or regional offices and shall be used only as a guide for individual preparation.

Board of Contract Appeals

General Services Administration
Washington, D.C. 20405

SUBPOENA

OMB APPROVAL NO.
3090-0221

_____ GSBCA_____

_____

_____

Contract/Solicitation No.

_____

TO: _____

_____

_____

YOU ARE HEREBY COMMANDED to appear at _____ (Room Number) _____ (Building)

_____ (Street Number) _____ (City) _____ (State)

at _____o'clock _____.m., on the _____ day of _____, 19____,

to testify at a (deposition/hearing) in this case; and to bring with you [1] _____

_____

_____

_____

and to stay there until given permission to leave. This subpoena is issued at the request of (Appellant/Petitioner/Applicant/Respondent).

Your appearance as ordered by this subpoena will entitle you to receive the fees and mileage provided by 28 U.S.C. § 1821 or other applicable law.

_____

[1] Strike the words "and bring with you" unless the subpoena is to require the production of documents or tangible things, in which case the documents and things should be designated in the blank space provided for that purpose. If testimony by an organization representative or designee is requested, describe with reasonable particularity the matters on which examination is requested.

GENERAL SERVICES ADMINISTRATION **GSA** FORM 9534 (Rev. 11-93)
Prescribed by BCA 2806.1

Upon written request to this Board by you or by a party to this case, which request should be made within 10 days after service but in any event no later than the time specified in the subpoena for attendance, the Board may (i) quash or modify the subpoena if it is unreasonable and oppressive or for other good cause shown, or (ii) require the party in whose behalf the subpoena was issued to advance the reasonable cost of producing subpoenaed books, papers, documents, or tangible things.

(Board Judge)	(Date)
(Representative for Appellant/Petitioner/Applicant)	(Representative for Respondent)
(Address)	(Address)
(Telephone Number)	(Telephone Number)
(Date)	(Date)

RETURN ON SERVICE

Summoned the above-named witness by delivering a copy to h___ and tendering to h___ the fees for one days attendance and mileage allowed by law, on the _____ day of _____, 19_____, at _____.

Subscribed and sworn to before me, a _____ this _____ day of _____, 19_____.

_____

NOTE: Affidavit not required if service is made by U.S. Marshall or Deputy. Service may also be made by any other person who is not a party and is not less than 18 years of age. Service shall be made by personally delivering a copy to the person named and tendering the fees for one day's attendance and the mileage allowed by law; however, where the subpoena is issued on behalf of the Government, money payments need not be tendered in advance of attendance.

GSA FORM 9534 BACK (REV. 11-93)

Board of Contract Appeals

General Services Administration
Washington, D.C. 20405

Form 4

_____ :
_____ : GSBCA _____
_____ :
Contract/Solicitation No. :
_____ :

GOVERNMENT CERTIFICATE OF FINALITY

A. Date claim(s) filed with the contracting officer:

B. Amount to be paid: $ _____.

C. Agency address (regional office if other than central office):

D. Agency Certification

_____ hereby certifies that:

(1) it has not initiated and will not initiate any proceeding at the Board for the reconsideration of, or relief from, this award;

(2) it has not initiated and will not initiate any appeal of this award to the United States Court of Appeals for the Federal Circuit.

Government Agency

_____ **By _____**
Date **Signature and Title**

Note: This format shall not be printed, reproduced, or stocked by the Central office or regional offices and shall be used only as a guide for individual preparation.

Board of Contract Appeals

General Services Administration
Washington, D.C. 20405

Form 5

_____	:	
_____	:	GSBCA _____
_____	:	
	:	
Contract/Solicitation No.	:	
	:	
_____	:	

APPELLANT/APPLICANT CERTIFICATE OF FINALITY

A. Address to which check should be sent (if check is to be sent to counsel, enclose a power of attorney):

B. Appellant/Applicant Certification

_____hereby certifies that:

(1) it has not initiated and will not initiate any proceeding at the Board for the reconsideration of, or relief from, this award;

(2) it has not initiated and will not initiate any appeal of this award to the United States Court of Appeals for the Federal Circuit; and

(3) it agrees to accept the amount awarded, plus any interest awarded, in accordance with the Board's decision in this case, in full and final satisfaction of its case.

Appellant/Applicant

_____ **By** _____

Date **Signature and Title**

Note: This format shall not be printed, reproduced, or stocked by the Central office or regional offices and shall be used only as a guide for individual preparation.

BILLING CODE 6829–AL–C

2. Part 6102 is added to read as follows:

PART 6102—RULES OF PROCEDURE OF THE GENERAL SERVICES ADMINISTRATION BOARD OF CONTRACT APPEALS (EXPEDITED PROCEEDINGS)

Sec.
6102.1 Variation from standard proceedings [Rule 201].
6102.2 Small claims procedure [Rule 202].
6102.3 Accelerated procedure [Rule 203].
6102.4 Alternative dispute resolution [Rule 204].

Authority: 41 U.S.C. 601–613.

6102.1 Variation from standard proceedings [Rule 201].

The ultimate purpose of any Board proceeding is to resolve fairly and expeditiously any dispute properly before the Board. When, during the normal course of a Board proceeding, the parties agree that a change in established procedure will promote this end, the Board will make that change if it is deemed to be feasible and in the best interest of the parties, the Board, and the resolution of contract disputes. The following are examples of these changes:

(a) Establishing an expedited schedule of proceedings, such as by limiting the times provided in part 6101 of this chapter for various filings, to facilitate a prompt resolution of the case;

(b) Developing a record and rendering a decision on the issue of entitlement prior to reviewing the issue of quantum in a party's claim;

(c) Developing a record and rendering a decision on any legal or factual issue in advance of others when that issue is deemed critical to resolving the case or effecting a settlement of any items in dispute; and

(d) Developing a record regarding relevant facts through an on-the-record round-table discussion with sworn witnesses, counsel, and the panel chairman rather than through formal direct and cross-examination of each of these same witnesses. This discussion shall be controlled by the panel chairman. It may be conducted, for example, through the presentation of narrative statements of witnesses or on an issue by issue basis. The panel chairman may also request that the parties' counsel or representatives present opening and/or closing statements in lieu of written briefs.

6102.2 Small claims procedure [Rule 202].

(a) *Election.*—(1) The small claims procedure is available solely at the appellant's election, and only when there is a monetary amount in dispute and that amount is $50,000 or less. Such election shall be made no later than 30 calendar days after the appellant's receipt of the agency answer, unless the panel chairman enlarges the time for good cause shown.

(2) At the request of the Government, or on its own initiative, the Board may determine whether the amount in dispute is greater than $50,000, such that the election is inappropriate. The Government shall raise any objection to the election no later than 10 working days after receipt of a notice of election.

(b) *Decision.* The panel chairman may issue a decision, which may be in summary form, orally or in writing. A decision which is issued orally shall be reduced to writing; however, such a decision takes effect at the time it is rendered, prior to being reduced to writing. A decision shall be final and conclusive and shall not be set aside except in case of fraud. A decision shall have no value as precedent.

(c) *Procedure.* Promptly after receipt of the appellant's election of the small claims procedure, the Board shall establish a schedule of proceedings that will allow for the timely resolution of the appeal. Pleadings, discovery, and other prehearing activities may be restricted or eliminated.

(d) *Time of decision.* Whenever possible, the panel chairman shall resolve an appeal under this procedure within 120 calendar days from the Board's receipt of the election. The time for processing an appeal under this procedure may be extended if the appellant has not adhered to the established schedule. Either party's failure to abide by the Board's schedule may result in the Board drawing evidentiary inference adverse to the party at fault.

6102.3 Accelerated procedure [Rule 203].

(a) *Election.*—(1) The accelerated procedure is available solely at the appellant's election, and only when there is a monetary amount in dispute and that amount is $100,000 or less. Such election shall be made no later than 30 calendar days after the appellant's receipt of the agency answer, unless the panel chairman enlarges the time for good cause shown.

(2) At the request of the Government, or on its own initiative, the Board may determine whether the amount in dispute is greater than $100,000, such that the election is inappropriate. The Government shall raise any objection to the election no later than 10 working days after receipt of a notice of election.

(b) *Decision.* Each decision shall be rendered by the panel chairman with the concurrence of one of the other judges assigned to the panel; in the event the two judges disagree, the third judge assigned to the panel will participate in the decision.

(c) *Procedure.* Promptly after receipt of the appellant's election of the accelerated procedure, the Board shall establish a schedule of proceedings that will allow for the timely resolution of the appeal. Pleadings may be simplified, and discovery and other prehearing activities may be restricted or eliminated.

(d) *Time of decision.* Whenever possible, the panel chairman shall resolve an appeal under this procedure within 180 calendar days from the Board's receipt of the election. The time for processing an appeal under this procedure may be extended if the appellant has not adhered to the established schedule. Either party's failure to abide by the Board's schedule may result in the Board drawing evidentiary inferences adverse to the party at fault.

6102.4 Alternative dispute resolution [Rule 204].

(a) *Availability of ADR procedures.* The Board will make its services available for ADR proceedings in contract and procurement matters involving any agency, regardless of whether the agency uses the Board to resolve its Contract Disputes Act appeals.

(1) *ADR subsequent to docketing of case at the Board.* Parties are encouraged to consider the feasibility of using ADR as soon as their case is docketed. If, however, at any time during the course of a Board proceeding, the parties agree that their dispute may be resolved through the use of an ADR technique, the panel chairman may suspend proceedings for a reasonable period of time while the parties and the Board attempt to resolve the dispute in this manner. The use of an ADR technique will not toll any relevant statutory time limit for deciding the case.

(2) *Other ADR.* Upon request, the Board will make a Board Neutral available for an ADR proceeding involving any agency in any contract or procurement matter at any stage of a procurement, even if no contracting officer decision has been issued or is contemplated. To initiate an ADR proceeding, the parties shall jointly request the ADR in writing and direct such request to the Office of the Clerk of the Board. For agencies other than GSA, the Board will provide ADR services on a reimbursable basis.

(b) *Conduct of ADR.*—(1) *Selection of Board Neutral.* If ADR is agreed to by

the parties and the Board, the parties may request the appointment of one or more Board judges to act as a Board Neutral or Neutrals. The parties may request that the Board's chairman appoint a particular judge or judges as the Board Neutral, or ask the Board's chairman to appoint any judge or judges as the Neutral. If, when ADR has been requested for a case that has already been docketed with the Board, as provided in paragraph (a)(1) of this section, the parties may request that the panel chairman serve as the Board Neutral. In such a situation, if the ADR is unsuccessful,

(i) If the ADR has involved mediation, the panel chairman shall not retain the case, and

(ii) If the ADR has not involved mediation, the panel chairman, after considering the parties' views, shall decide whether to retain the case.

(2) *Retention and confidentiality of materials.* The Board will review materials submitted by a party for an ADR proceeding, but will not retain such materials after the proceeding is concluded or otherwise terminated. Material created by a party for the purpose of an ADR proceeding is to be used solely for that proceeding unless the parties agree otherwise. Parties may request a protective order in an ADR proceeding in the manner provided in 6101.12(h).

(c) *Types of ADR.* ADR is not defined by any single procedure or set of procedures. The Board will consider the use of any technique proposed by the parties which is deemed to be fair, reasonable, and in the best interest of the parties, the Board, and the resolution of contract disputes. The following are examples of available techniques:

(1) *Mediation.* The Board Neutral, as mediator, aids the parties in settling their case. The mediator engages in *ex parte* discussions with the parties and facilitates the transmission of settlement offers. Although not authorized to render a decision in the dispute, the mediator may discuss with the parties, on a confidential basis, the strengths and weaknesses of their positions. No judge who has participated in discussions about the mediation will participate in a Board decision of the case if the ADR is unsuccessful.

(2) *Neutral case evaluation.* The parties agree to present to the Board Neutral information on which the Board Neutral bases a non-binding, oral, advisory opinion. The manner in which the information is presented will vary from case to case depending upon the agreement of the parties. Presentations generally fall between two extremes, ranging from an informal proffer of evidence together with limited argument from the parties to a more formal presentation of oral and documentary evidence and argument from counsel, such as through a mini-trial.

(3) *Binding decision.* One or more Board judges render a decision which, by prior agreement of the parties, is to be binding and non-appealable. As in the non-binding evaluation of a case by a Board Neutral, the manner in which information is presented for a binding decision may vary depending on the circumstances of the particular case.

(4) *Other procedures.* In addition to other ADR techniques, including modifications to those listed in this section, as agreed to by the Board and parties, the parties may use ADR techniques that do not require direct Board involvement.

(5) *Selective use of standard procedures.* Parties considering the use of ADR are encouraged to adapt for their purposes any provisions in part 6101 which they believe will be useful. This includes but is not limited to provisions concerning record submittals, pretrial discovery procedures, and hearings.

Dated: September 26, 1996.

Robert W. Parker,

Vice Chairman.

[FR Doc. 96–25121 Filed 10–4–96; 8:45 am]

BILLING CODE 6829–AL–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AC01

Endangered and Threatened Wildlife and Plants; Determination of Endangered or Threatened Status for Four Southern Maritime Chaparral Plant Taxa from Coastal Southern California and Northwestern Baja California, Mexico

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The U.S. Fish and Wildlife Service (Service) determines endangered status pursuant to the Endangered Species Act of 1973, as amended (Act), for two plants—*Arctostaphylos glandulosa* ssp. *crassifolia* (Del Mar manzanita) and *Chorizanthe orcuttiana* (Orcutt's spineflower) throughout their historic range in southwestern California and northwestern Baja California, Mexico; and threatened status for two plants—*Verbesina dissita* (big-leaved crown-beard) and *Baccharis vanessae* (Encinitas baccharis) throughout their historic range in southwestern California and northwestern Baja California, Mexico. These four taxa are threatened by one or more of the following—trampling by farm workers or recreational activities; fuel modification; competition from non-native plant species; and habitat destruction due to residential, agricultural, commercial, and recreational development. Several of these plant taxa are also threatened by a risk of extinction from naturally occurring events due to their small population size and limited distribution. This rule implements the Federal protection and recovery provisions afforded by the Act for these four plants.

EFFECTIVE DATE: November 6, 1996.

ADDRESSES: The complete file for this rule is available for public inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Carlsbad Field Office, 2730 Loker Avenue West, Carlsbad, California 92008.

FOR FURTHER INFORMATION CONTACT: Fred Roberts, Botanist (see **ADDRESSES** section) (telephone: 619/431-9440).

SUPPLEMENTARY INFORMATION:

Background

Southern maritime chaparral is a low, fairly open chaparral typically dominated by *Ceanothus verrucosus* (wart-stemmed ceanothus), *Xylococcus bicolor* (mission manzanita), *Adenostoma fasciculatum* var. obtusifolium (chamise), *Quercus dumosa* (Nuttall's scrub oak), *Cneoridium dumosum* (bush rue), *Rhamnus crocea* (red berry), *Yucca schidigera* (Mojave yucca), and occasionally *Dendromecon rigida* (bush poppy)(Holland 1986; Todd Kehler-Wolf, Plant Ecologist, California Department of Fish and Game (CDFG), pers. comm., 1993; Dan Kelly and Patricia Gordon-Reedy, biologists, OGDEN, pers. comm., 1993). Southern maritime chaparral is a plant association that occurs only in coastal southern California along the immediate coast of San Diego and Orange counties and northwestern Baja California, Mexico. The distribution of southern maritime chaparral in Orange County is disjunct, and the species composition is slightly different from that found in San Diego County and Mexico (Gray and Bramlet 1992).

Southern maritime chaparral is considered to be a unique and

threatened plant community. It has been estimated that about 120 hectares (ha) (300 acres (ac)) of southern maritime chaparral occurred historically in Orange County (U.S. Fish and Wildlife Service (USFWS), unpublished data), while about 8,400 ha (21,000 ac) of southern maritime chaparral occurred historically in San Diego County (Oberbauer and Vanderwier 1991). Currently, there are an estimated 60 ha (150 ac) of southern maritime chaparral in Orange County (Todd Kehler-Wolf, pers. comm., 1993) and between 600 and 1,480 ha (1,500 and 3,700 ac) in San Diego County (Oberbauer and Vanderwier 1991; OGDEN 1993; Dave Hogan, Southwest Center for Biological Diversity, *in litt.*, 1993). This represents an 82 to 93 percent decline in habitat in southern California, largely due to agricultural conversion and urbanization. Much of the remaining 10 to 20 percent of the United States portion of southern maritime chaparral is located on Carmel Mountain, Torrey Pines State Park, and in the cities of Carlsbad and Encinitas in San Diego County. The distribution of southern maritime chaparral and related associations has also declined significantly in Baja California, Mexico, for many of the same reasons.

One of the four plant taxa to be listed by this final rule, *Chorizanthe orcuttiana*, is primarily restricted to weathered sandstone bluffs in association with or in microhabitats within southern maritime chaparral. This species is endemic to south-central and southern coastal San Diego County, California. A second taxon, *Arctostaphylos glandulosa* ssp. *crassifolia*, is also primarily associated with southern maritime chaparral in San Diego County, California. It also occurs in disjunct populations in northwestern Baja California, Mexico, at least as far south as Mesa el Descanseo, 40 kilometers (km) (25 miles (mi)) north of Ensenada.

The remaining two taxa, *Verbesina dissita* and *Baccharis vanessae*, are frequently associated with southern maritime chaparral but also extend into other plant communities. *Verbesina dissita* is restricted to rugged coastal canyons in association with San Onofre breccia-derived soils in the southern maritime chaparral of southern Orange County, California. This taxon also occurs in limited numbers in Venturan-Diegan transitional coastal sage scrub (Gray and Bramlet 1992), Diegan coastal sage scrub, and southern mixed chaparral (Holland 1986). *Verbesina dissita* occurs disjunctly in similar vegetation associations from Punta Descanso south to San Telmo in northwestern Baja California, Mexico. *Baccharis vanessae* occurs in southern maritime chaparral in the vicinity of Encinitas, central San Diego County, California, and extends inland to Mount Woodson and Poway where it is associated with dense southern mixed chaparral. One population of this plant occurs in the Santa Margarita Mountains of northern San Diego County. Two of the four taxa are found below 250 meters (m) (820 feet (ft)) in elevation in the United States. *Arctostaphylos glandulosa* ssp. *crassifolia* reaches 730 m (2,400 ft) elevation in Mexico. *Baccharis vanessae* is known to occur at 880 m (2,890 ft) in elevation on Mount Woodson.

While three of the four plant taxa are largely restricted to the United States, 85 percent of the known populations of *Verbesina dissita* are known from northwestern Baja California, Mexico. Although the status of this species and its habitat in Mexico is not well documented, over 20 percent of the populations occuring in Mexico have been extirpated. Agricultural conversion, resort and residential development, and wide fuel breaks and slash and burn practices have already affected and continue to contribute to the decline of *Verbesina dissita* in Mexico (CDFG 1990, Oberbauer 1992).

The natural plant communities of coastal Orange and San Diego Counties have undergone significant changes resulting from both human-caused activities and natural events. The rapid urbanization of southern Orange County and south-central San Diego County has already eliminated a significant portion of the southern maritime chaparral and the four plant taxa considered herein. Fire also plays an important role in determining southern California plant community distribution and composition. The advent of widespread urbanization and the disruption in natural fire cycles potentially threatens the remaining southern maritime chaparral. Populations of these four taxa have been subjected to a considerable degree of fragmentation.

Discussion of the Four Taxa

Arctostaphylos glandulosa ssp. *crassifolia* (Del Mar manzanita), a member of the heath family (Ericaceae), is one of six recognized subspecies occurring in California and northwest Baja California, Mexico (Wells 1987, 1993). The subspecies is an erect shrub, generally 1 to 1.2 m (3.3 to 4 ft) tall, but occasionally higher when introgressed (influenced by other subspecies).

This taxon is distinguished from other subspecies of *Arctostaphylos glandulosa* by its shorter stature (other subspecies are up to 2.5 m (8.2 ft) tall), and by its dark gray-green leaves that are glabrate above and tomentulose beneath. The branchlets and leaf-like bracts are non-glandular and tomentulose with scattered long hairs or bristles (Wells 1993). Generally, *A. glandulosa* (Eastwood manzanita) is a relatively open, smooth, dark red-barked shrub characterized by a basal burl and scarcely leaf-like bracts that are shorter than the hairy flower-stalks. Four of six subspecies of *A. glandulosa* lack non-glandular, tomentulose hairs and scattered white bristles on the branchlets, bracts and leaves. Of the remaining two taxa, *A. g.* ssp. *mollis* of the western Transverse Ranges has more uniformly distributed, long, white bristles and bright green, smooth and shiny leaves, while *A. g.* ssp. *glaucomollis* of the San Gabriel and San Bernardino Mountains lacks leaf-like bracts (Wells 1993).

Arctostaphylos glandulosa ssp. *crassifolia* was first described by Willis Jepson (1922) based on a specimen he collected in Del Mar, California. In 1925, Jepson placed Del Mar manzanita under the name *Arctostaphylos tomentosa* var. *crassifolia* (Knight 1981). This name was used by Howard McMinn (1939), who stated that Del Mar manzanita ''seems very closely related to *A. glandulosa* var. *cushingiana* but the more truncate leaf-bases, the usually more tomentulose lower leaf-surfaces, and distribution seem sufficient to maintain it as a variety of *A. tomentosa*.'' J.E. Adams, in his 1940 treatment of the genus *Arctostaphylos*, transferred var. *crassifolia* to *A. glandulosa* as in Jepson's original treatment (Knight 1981).

Philip Wells (1968) stated that ''other morphological variants of the *A. glandulosa* complex have largely allopatric (do not overlap) geographic distributions and are recognized as subspecies.'' Accordingly, Wells applied the name *A. glandulosa* ssp. *crassifolia* to the Del Mar manzanita. Subsequent taxonomic review (Munz 1959, 1974) upheld this treatment. Walter Knight (1981) reviewed the morphology and summarized the taxonomic history of *A. g.* ssp. *crassifolia*. While the majority of Knight's discussion in that article supported the validity of *A. g.* ssp. *crassifolia*, Knight concluded that this taxon should not be recognized. He stated that *A. g.* ssp. *crassifolia* was a product of hybridization between *A. glandulosa* and other manzanita species in the area. However, Knight's conclusions were not widely accepted by botanists in San Diego County (Beauchamp 1986; Thomas Oberbauer, Planner, County of San Diego, pers.

comms., 1993, 1994). Knight did not offer support, nor discuss potential parentage for considering *A. g.* ssp. *crassifolia* as a hybrid entity. *Arctostaphylos glandulosa* ssp. *crassifolia* is allopatric with other manzanita taxa, except in Mexico, where the range is partly sympatric (overlapping) with *A. g.* ssp. *zacaensis* (Wells 1987). Additionally, the morphological characters of *A. g.* ssp. *crassifolia* do not appear to be intermediate with any other species within the vicinity of its range (McMinn 1939, Munz 1974, Wells 1993, Roberts 1994).

Both Knight and Wells were asked to examine populations of manzanita along coastal San Diego County in March 1986. From these field observations, Knight revised his position and agreed with the classical treatment, concluding that *Arctostaphylos glandulosa* ssp. *crassifolia* was distinct (T. Oberbauer, pers. comms., 1993, 1994; Jim Bartel, USFWS, pers. comm., 1994). Wells reaffirmed the distinctness of *A. g.* ssp. *crassifolia*, stating ''(*A. g.*) ssp. *crassifolia* is one of the more consistent and well-defined taxa within the variable *A. glandulosa* complex, and (*A. g.* ssp.) *crassifolia* has a discrete distribution, allopatric from other taxa'' (Wells 1987, Sweetwater Environmental Biologists (SEB) 1993b).

Arctostaphylos glandulosa ssp. *crassifolia* is restricted to sandstone terraces and bluffs from Carlsbad south to Torrey Pines State Park, extending inland to Rancho Santa Fe and Del Mar Mesa in San Diego County, California. An additional population has been reported just south of the San Dieguito River southwest of Lake Hodges. This species has been reported from five localities in northwestern Baja California, Mexico, from just east of Tijuana along the United States border, to Cerro el Coronel and Mesa Descanseo 40 km (25 mi) south of the United States border. These populations may no longer be extant due to considerable urban and agricultural development in the Tijuana vicinity (Roberts 1992). The most recent collection in the San Diego Museum of Natural History was made by Reid Moran in 1982.

About 1982, approximately 16,600 to 17,600 individuals of *Arctostaphylos glandulosa* ssp. *crassifolia* were known to be distributed over about 26 population centers (Roberts 1992, SEB 1993b, OGDEN 1995a). A significant number of these populations have been severely impacted since then. For example, in 1987, one population of nearly 500 individuals near San Dieguito Creek and the surrounding southern maritime chaparral habitat was cleared and converted to agriculture. Cultivation at this site was active for one season and has not been continued (T. Oberbauer, pers. comm., 1992). Currently, about 9,400 to 10,300 individuals, scattered roughly throughout the historic distribution of the species in San Diego County, are known to be extant (Roberts 1993, SEB 1993b, OGDEN 1995a). About 75 percent of all remaining individuals are located within six concentrations. The majority of the 26 populations are found on private land, four occur in State, county or local parks, and none are known from Federal lands. The number of individuals in Baja California, Mexico, is not known but is likely to be smaller than in the United States, based on the limited availability of habitat.

Four populations of *Arctostaphylos glandulosa* totaling approximately 3,000 individuals in the vicinity of Miramar Reservoir have been attributed to *A. g.* ssp. *crassifolia*, but Wells (pers. comm., 1992) maintains that these plants are intermediate with other subspecies of *A. glandulosa* and can not be definitely placed. Later inclusion of these populations in *A. g.* ssp. *crassifolia* would not significantly alter the findings of this rule. Nearly 50 percent of the individuals known from the vicinity of Miramar Reservoir in 1982 were eliminated by the Scripps Ranch development between 1989 and 1992.

Baccharis vanessae (Encinitas baccharis), a member of the sunflower family (Asteraceae), is a dioecious broom-like shrub, 0.5 to 1.3 m (1.6 to 4.3 ft) tall. It was discovered by Mitchel Beauchamp in October 1976 in southern maritime chaparral on Eocene sandstones along the north side of Encinitas Boulevard in Encinitas. The species was later described by Beauchamp (1980). *Baccharis vanessae* is distinguished from other members of the genus by its filiform leaves and delicate phyllaries which are reflexed at maturity (Beauchamp 1980, Munz 1974).

As currently understood, the historical distribution of this species included 19 natural populations scattered from Encinitas east through the Del Dios highlands and Lake Hodges area to Mount Woodson and south to Poway and Carmel Mountain in San Diego County, California. Fourteen of these populations are still extant and contain approximately 2,000 individuals in total (CDFG 1992). Four of these populations, however, contain fewer than six individuals each. An additional disjunct individual was discovered on the western slopes of Carmel Mountain in 1993 (D. Hogan, *in litt.*, 1993). This location harbors the southernmost known population. A single transplanted population of 34 individuals was established in San Dieguito Park, but this population has not persisted (Hall 1987). The majority of the remaining populations are on private lands.

Chorizanthe orcuttiana (Orcutt's spineflower) was first described by Charles Parry in 1884 based on a specimen collected by Charles Orcutt at Point Loma, San Diego County, in the same year (Parry 1884). *Chorizanthe orcuttiana* is a low, yellow-flowered annual of the buckwheat family (Polygonaceae) restricted to sandy soils. It is distinguished from other members of the genus by its prostrate form, campanulate three-toothed involucre and involucral awns that are hooked near the tip (Reveal 1989).

Historically, *Chorizanthe orcuttiana* is known from 10 separate localities in San Diego County from Point Loma near San Diego (including the U.S. Naval Reservation), Del Mar, Kearney Mesa and Encinitas (CDFG 1992). Only two populations have been seen in recent years. Allen reported 50 to 100 individuals at Torrey Pines State Park in 1987 (CDFG 1992). However, this population has not been relocated in the last several years, possibly due to changing plant species composition and density as result of a 1984 burn. The species was thought to be extinct until a new population was discovered in 1991 at Oak Crest Park in Encinitas (D. Hogan, *in litt.*, 1991). This population numbered fewer than 40 individuals in 1993 and fewer than 10 individuals in 1994, and it is distributed over a relatively small area (about 4 square m (43 square ft)) (unpublished USFWS data). The number of individuals varies widely from year to year because the success of germination is highly dependent on factors such as rainfall, which often differ significantly from one year to the next in southern California.

Verbesina dissita (big-leaved crown-beard) was first described by Asa Gray (1885) based on a collection made by Charles Orcutt at Ensenada, Baja California, Mexico, in September 1884. The taxon apparently was first collected in the United States at Arch Beach in South Laguna, Orange County, in 1903 by Mrs. M.F. Bradshaw (Hall 1907).

Verbesina dissita, a member of the sunflower family (Asteraceae), is a low, semi-woody perennial shrub with bright yellow flowers. This species grows from 0.5 to 1.0 m (1.6 to 3.3 ft) tall and has distinctive scabrid leaves. *Verbesina dissita* is distinguished from other members of the genus in California and Baja California, Mexico, by its naked

achenes and broad involucre (Munz 1974).

Verbesina dissita is found on rugged hillsides in dense maritime chaparral from Laguna Beach in Orange County south to the San Telmo area east of Cabo Colonet in Baja California, Mexico. In California it is known from two population centers less than 3.2 km (2 mi) apart. Because of the low growth habit and preference for understory locations, the population size of this taxon is difficult to estimate. The United States populations have been estimated to contain several thousand plants (CDFG 1992, Marsh 1992). Historically, this taxon has been recorded from 23 separate locations in Mexico. Of the Mexican localities, over 20 percent, all north of Punta Santo Tomas, have been eliminated. Nearly all known populations are on private land.

Previous Federal Action

Action by the Federal government on two of the four plant taxa contained herein began pursuant to section 12 of the Endangered Species Act of 1973 (Act), as amended (16 U.S.C. 153 *et seq.*). Section 12 directed the Secretary of the Smithsonian Institution to prepare a report on those plants considered to be endangered, threatened or extinct. This report, designated as House Document No. 94–51, was presented to Congress on January 9, 1975, and included *Arctostaphylos glandulosa* ssp. *crassifolia* and *Chorizanthe orcuttiana* as endangered. The Service published a notice in the July 1, 1975, Federal Register (40 FR 27823) of its acceptance of the report of the Smithsonian Institution as a petition within the context of section 4(c)(2) (petition provisions are now found in section 4(b)(3) of the Act) and its intention thereby to review the status of the plant taxa named therein. On June 16, 1976, the Service published a proposal in the Federal Register (42 FR 24523) to determine approximately 1,700 vascular plants to be endangered species pursuant to section 4 of the Act. *Chorizanthe orcuttiana* and *Arctostaphylos glandulosa* ssp. *crassifolia* were included in the June 16, 1976, Federal Register notice.

General comments received in response to the 1976 proposal were summarized in an April 26, 1978, Federal Register notice (43 FR 17909). The Endangered Species Act Amendments of 1978 required that all proposals already over two years old be withdrawn. A 1-year grace period was given to those proposals already more than two years old. In the December 10, 1979, Federal Register (44 FR 70796), the Service published a notice of withdrawal of the portion of the June 8, 1976, proposal that had not been made final, along with four other proposals that had expired.

The Service published an updated notice of review of plants on December 15, 1980 (45 FR 82480). This notice included *Baccharis vanessae* and *Chorizanthe orcuttiana* as category 1 taxa. Category 1 taxa are those taxa for which substantial information on biological vulnerability and threats are available to support preparation of listing proposals. On November 28, 1983, the Service published in the Federal Register a supplement to the Notice of Review (48 FR 53840), in which B. *vanessae* and *C. orcuttiana* were reclassified from category 1 to category 2. Category 2 candidates were taxa for which data in the Service's possession indicated listing was possibly appropriate but for which substantial information on biological vulnerability and threats was not known or on file to support the preparation of proposed rules. The designation of category 2 species was not included in the latest notice of review (February 28, 1996; 61 FR 7596). *Arctostaphylos glandulosa* ssp. *crassifolia* was not included in either the 1980 review list or the 1983 supplement.

The plant notice was again revised on September 27, 1985 (50 FR 39526), and *Arctostaphylos glandulosa* ssp. *crassifolia* was listed as a category 3B taxon. Category 3B taxa were those taxa that, based upon current taxonomic understanding, did not represent distinct taxa under the Act's definition of species (the designation of category 3B has also been discontinued). This change reflected the questionable validity of the taxon as presented by Knight (1981). The taxonomy of *Arctostaphylos glandulosa* ssp. *crassifolia* was subsequently reevaluated, and the plant was included as a category 2 taxon in the February 21, 1990, Plant Notice of Review (55 FR 6184), based on the work of Wells (1987). In this same notice, *Baccharis vanessae* and *Chorizanthe orcuttiana* were reevaluated and included as category 1 species based on information contained in status reports prepared in conjunction with State listing as endangered. The 1990 review included *C. orcuttiana* as a category 1* candidate, indicating that this species was possibly extinct. Based on additional information on threats and vulnerability, the Service elevated A. g. ssp. *crassifolia* and *C. orcuttiana* to category 1 and added *Verbesina dissita* as a category 1 candidate in the September 30, 1993, Notice of Review (58 FR 51144).

Section 4(b)(3)(B) of the Act requires the Secretary to make certain findings on pending petitions within 12 months of their receipt. Section 2(b)(1) of the 1982 amendments further requires that all petitions pending on October 13, 1982, be treated as having been newly submitted on that date. This was the case for *Arctostaphylos glandulosa* ssp. *crassifolia* and *Chorizanthe orcuttiana* because the 1975 Smithsonian report had been accepted as a petition. On October 13, 1983, the Service found that the petitioned listing of these species was warranted, but precluded by other pending listing actions pursuant to section 4(b)(3)(B)(iii) of the Act. Notification of this finding was published in the Federal Register on January 20, 1984 (49 FR 2485). Such a finding requires the petition to be recycled, pursuant to section 4(b)(3)(C)(i) of the Act. The finding was reviewed in October of 1984, 1985, 1987, 1988, 1989, 1990, 1991, and 1992. Publication of the proposed rule constituted the warranted finding for these taxa.

On December 14, 1990, the Service received a petition dated December 5, 1990, from Mr. David Hogan of the San Diego Biodiversity Project, to list *Baccharis vanessae* as an endangered species. The petition also requested the designation of critical habitat. The Service evaluated the petitioner's requested action and published a 90-day finding on August 30, 1991 (56 FR 42968), stating that substantial information had been presented that the requested actions concerning *Baccharis vanessae* may be warranted.

A proposed rule to list *Arctostaphylos glandulosa* ssp. *crassifolia, Baccharis vanessae,* and *Chorizanthe orcuttiana* as endangered and *Verbesina dissita* as threatened was published in the Federal Register on October 1, 1993 (58 FR 51302). That proposed rule also included *Dudleya blochmaniae* ssp. *brevifolia* (short-leaved dudleya) to be listed as endangered and *Corethrogyne filaginifolia* var. *linifolia* (Del Mar sand-aster) to be listed as a threatened taxon. The proposals to list those two taxa are withdrawn and addressed in a document published concurrently in the proposed rule section of this issue of the Federal Register.

The processing of this final rule follows the Service's listing priority guidance published in the Federal Register on May 16, 1996 (61 FR 24722). The guidance clarifies the order in which the Service will process rulemakings following two related events: 1) the lifting, on April 26, 1996, of the moratorium on final listings imposed on April 10, 1995 (Public Law

104–6), and 2) the restoration of significant funding for listing through passage of the omnibus budget reconciliation law on April 26, 1996, following severe funding constraints imposed by a number of continuing resolutions between November 1995 and April 1996. The guidance calls for prompt processing of final rules containing species facing threats of high magnitude. All four taxa in this rule face high magnitude threats.

Summary of Comments and Recommendations

In the October 1, 1993, proposed rule (58 FR 51302) and associated notifications, all interested parties were requested to submit factual reports or information that might contribute to the development of a final rule. A 90-day comment period closed on January 1, 1994. Appropriate State agencies, county governments, Federal agencies, and other interested parties were contacted and requested to comment. A letter of notification and a copy of the proposed rule were also sent to the government of Mexico. Public notices announcing the publication of the proposed rule were published in the *Press-Enterprise* in Riverside County on October 12, 1993, and the *San Diego Union Tribune* in San Diego County and the *Orange County Register* on October 13, 1993. No request for a public hearing was received.

A total of seven written comments were received. Two commenters supported the listing of these taxa. Two commenters neither supported nor opposed the proposed listing. Three commenters opposed the proposed listing. Information from a number of these comments has been incorporated into the final rule. Eleven relevant issues were raised in these comments and the Service's response to each is as follows:

Issue 1: One commenter stated that the estimate for remaining southern maritime chaparral was too high and suggested that the definition of southern maritime chaparral adopted by the Service, based on Holland (1986), required modification.

Service Response: A range of estimates for remaining southern maritime chaparral has been incorporated into the final rule. While the exact amount of remaining southern maritime chaparral is not agreed upon, the Service considers this plant association to be sensitive and rare. The Service has coordinated with the CDFG, knowledgeable biologists, and other parties in determining an appropriate definition for southern maritime chaparral (Jim Dice, CDFG, T. Keeler-Wolf, D. Kelly and P. Gordon-Reedy, pers. comms., 1993).

Issue 2: One commenter argued that *Arctostaphylos glandulosa* ssp. *crassifolia* does not warrant protection under the Act because the Service has failed to demonstrate that it is a distinct taxon. The commenter claimed that there was no consensus within the scientific community regarding this taxon. The commenter stated that the Service did not clearly demonstrate that Knight's treatment (Knight 1981) should be rejected over Wells (1987, 1993). The commenter questioned the use of morphological variation in determining subspecific classification. Additionally, the commenter claimed that it is unclear whether the Scripps Ranch population of *Arctostaphylos glandulosa* is representative of this taxon.

Service Response: A discussion regarding the taxonomic history of this taxon is included under the ''Discussion of the Four Taxa'' section of this rule. The discussion in the proposed rule has been expanded to increase clarity and address concerns included within this comment. In determining the taxonomic status of any taxon, the Service utilizes the best available information. Nearly all taxonomic treatments published since the original description of *Arctostaphylos glandulosa* ssp. *crassifolia* in 1922 recognize this taxon as distinct. The two most recent treatments (Wells 1987, 1993) are the accepted, peer reviewed treatments for this genus. This taxon is also recognized as distinct in local floras (Beauchamp 1986) and other reports regarding the status of the taxon (SEB 1993b).

The Service does not rely on Knight (1981) because this treatment does not represent the best available information. As discussed under the ''Background'' section of this rule, Knight did not substantiate his claim that *Arctostaphylos glandulosa* ssp. *crassifolia* was of hybrid origin between *A. glandulosa* and other unidentified species of *Arctostaphylos*. Furthermore, Knight reversed his opinion in 1986 and accepted *A. g.* ssp. *crassifolia* as valid (T. Oberbauer, pers. comm., 1993; J. Bartel, pers. comm., 1994). Wells (1968, 1993) published in peer-reviewed publications while Knight (1981) did not. Both Wells and Knight applied morphological variation in determining the status of *A. g.* ssp. *crassifolia*. While the Service acknowledges that other methods (i.e., chemotaxonomy and genetic analysis) may be used as supplements to morphological variation as available tools for taxonomic definition, morphological variation has historically been the most widely accepted basis for taxonomic distinction for all biological organisms.

Issue 3: One commenter claimed that historic losses of *Arctostaphylos glandulosa* ssp. *crassifolia* were the result of taxonomic confusion because of ''complete lack of consensus within the scientific community.'' The commenter noted the taxon has only recently been considered a distinct subspecies. The commenter also noted that the California Native Plant Society rejected this taxon in their 1988 Inventory (Smith and Berg 1988) and that the Service determined in the September 27, 1985, Notice of Review (50 FR 39528) that *A. g.* ssp. *crassifolia* did not represent a distinct taxon. The commenter also asserted that Federal recognition of this taxon has been lacking since the 1985 notice.

Service Response: As discussed under the ''Background'' section, this subspecies has been recognized as distinct for nearly 70 years. This taxon was first described as a variety of *A. glandulosa* in 1922, and has been widely recognized in taxonomic treatments since then (McMinn 1939; Abrams 1951; Munz 1959, 1974; Wells 1968, 1987, 1993; Beauchamp 1986). In 1985, the Service rejected this taxon based on the most recent taxonomic treatment at that time. However, since that time, floristic and monographic treatments by Beauchamp (1986) and Wells (1987) recognized *A. g.* ssp. *crassifolia* as a distinct taxon. The latter treatment detailed the taxonomic argument for retention of the subspecies. The Service, following the criteria of the best available information, reinstated the taxon to category 2 status in 1990. The California Native Plant Society currently recognizes *A. g.* ssp. *crassifolia* as a list 1B taxon (Skinner and Pavlik 1994). Plants included on list 1B are considered rare and endangered in the State of California and are eligible for State listing under California's Native Plant Protection Act (chapter 10 section 1901) or the State Endangered Species Act (Skinner and Pavlik 1994).

As discussed in this rule under ''Previous Federal Action,'' the commenter is incorrect in asserting that the Service has not identified this taxon as a candidate for protection under the Act since 1985. It was published as a category 2 candidate species in the February 21, 1990, Plant Notice of Review (55 FR 6184) and as a category 1 candidate in 1993. During the period between 1985 and 1990, *Arctostaphylos glandulosa* ssp. *crassifolia* was widely recognized in environmental documentation (Beauchamp 1986; Nelson 1988; Pacific Southwest Biological Services 1990; Stephen Lacy,

Biological Resource Manager, ERCE, *in litt*., 1991; T. Oberbauer, pers. comm., 1993). Based on the best available scientific and commercial information, the Service finds *A. g.* ssp. *crassifolia* to be a taxon eligible for listing under the Act.

Issue 4: Two commenters claimed that these taxa did not warrant listing as endangered or threatened because the majority of their populations are protected from development. One commenter dealt mainly with a species now being withdrawn from consideration for listing. Another commenter claimed that the report entitled ''Description, Status, Distribution, and Conservation of Del Mar Manzanita (*Arctostaphylos glandulosa* ssp. *crassifolia*)'' by Sweetwater Environmental Biologists (SEB 1993b), rebuts the Service's finding that listing of Del Mar manzanita is warranted. Based on this report, the commenters stated that the majority of these individuals (76 percent) occur within 7 of the 22 populations. Of these 7 major populations (each containing over 500 individuals), the commenters claimed that 82 percent will be preserved, which accounts for 70 percent of the entire taxon.

Service Response: Although these commenters evidently include *Baccharis vanessae, Chorizanthe orcuttiana*, and *Verbesina dissita* within the context of this comment, no specific discussion was included regarding these taxa.

The Service has considered the findings of the SEB report (1993b) in determining the status of *Arctostaphylos glandulosa* ssp. *crassifolia*. SEB reported that there were about 17,000 individuals of Del Mar manzanita distributed over 302 subpopulations within 24 populations in San Diego County from Oceanside south to La Jolla, and inland to Scripps Ranch in the United States. SEB described the range of this taxon as extending along the immediate coast of Baja California, Mexico, south to Cabo Colonet about 200 km (124 mi) south of the United States border.

Available data (Reid Moran, California Academy of Sciences, Philip Wells, T. Oberbauer, pers. comms., 1992; and herbarium collections at the San Diego Natural History Museum) indicate that the distribution of this taxon in Mexico is limited. The Service has not been presented with any evidence that *Arctostaphylos glandulosa* ssp. *crassifolia* occurs farther south than Mesa Descanseo 40 km (25 mi) south of the international border.

According to SEB (1993b), 22 of the 24 United States populations, 137 (45 percent) of the subpopulations and about 7,100 to 9,700 individuals (42 to 58 percent) of *Arctostaphylos glandulosa* ssp. *crassifolia* are still extant. SEB (1993b) further states that of the remaining individuals of this taxon, about 82 percent are proposed for conservation, which includes about 35 percent on public lands and 48 percent on private lands.

SEB (1993b) identify seven major populations that contain about three-fourths of all San Diego County *Arctostaphylos glandulosa* ssp. *crassifolia*. The Service concurs with the assessment of six of these populations and identifies the seventh population identified in SEB (1993b) as moderately large. Service staff assessed this population at fewer than 500 individuals in December 1993. The Service further considers that both the size and the configuration of these populations are important to the long-term viability of *A. g.* ssp. *crassifolia*. Currently all seven of the populations identified as large in SEB (1993b) are situated in natural blocks of vegetation greater than 40 ha (100 ac) in size.

The number of individuals in the SEB (1993b) report is not significantly different from, and generally conforms with, estimates used by the Service in preparation of the proposed rule. However, SEB (1993b) significantly overestimates the preserved population of *Arctostaphylos glandulosa* ssp. *crassifolia*. The remarks and data summary on Table 1 of the report are inconsistent—the data summary indicates that about 18 percent of this taxon is threatened by development, while the remarks section indicates that over 30 percent of the *A. g.* ssp. *crassifolia* is currently threatened by development. Although SEB (1993b) acknowledges that one of the major populations located in the city of Carlsbad, California, consists of nearly 2,000 individuals, only about 750 of these are accounted for in Table 1. The remaining 1,200 individuals are assumed to have been ''graded.'' However, these individuals are still extant and are threatened by the implementation of a large scale development project. The Service considers the loss of most of this population, which represents a reduction of 10 to 15 percent of the United States populations of *A. g.* ssp. *crassifolia*, to be a significant impact on this taxon. Nor is public open space necessarily equivalent to protection, as indicated in the SEB report. This is exemplified by clearing and mulching of southern maritime chaparral east of Palomar Airport (Ken Cory, USFWS, pers. comm., 1996) in an area identified as a public open space in Table 1 of the SEB report.

Estimates for preservation in SEB (1993b) do not consider the configuration of remaining occupied open space or edge effects resulting from existing and proposed development. The majority of the existing *Arctostaphylos glandulosa* ssp. *crassifolia* populations are relics of larger historic populations. Nearly 50 percent of the remaining populations, comprising about 10 to 14 percent of all individuals of *A. g.* ssp. *crassifolia*, are in open space parcels that are smaller than 20 ha (50 ac). While all populations of *A. g.* ssp. *crassifolia* are important, the majority of these small, isolated, and poorly configured populations are entirely within 60 m (200 ft) of, and are often surrounded by, development. These population configurations likely will not contribute significantly to the long-term preservation of the taxon. All are subject to edge effects (i.e., invasion of exotic plants, disturbances by local residents) and may be threatened by fuel modification activities (i.e., fire breaks, discing, reduction through thinning). The effect of isolation and habitat size reduction also retards natural fire and successional cycles within the habitat of *A. g.* ssp. *crassifolia* (Roberts 1993).

Of the larger and more significant populations of *Arctostaphylos glandulosa* ssp. *crassifolia*, only one population is protected and managed for long-term preservation (Torrey Pines State Park north). However, this population is located within a 80 ha (200 ac) parcel that is completely surrounded by development (Roberts 1993). Another population (Crest View Canyon) is under public management; however, about 50 percent of this population is located within 60 m (200 ft) of development and is subject to edge effects (Roberts 1993). While another population (upper end of Agua Hedionda) is also under public management, it is subject to incremental clearing impacts as a result of adjacent airport operations, road-widening activities, and clearing related to mulching and agriculture (Roberts 1994; K. Cory, pers. comm., 1996). This population is also bisected by numerous footpaths. At least 15 percent of this population is situated within 60 m (200 ft) of development (Roberts 1993).

Of the remaining four major populations, all are threatened in part by development and will be further fragmented or isolated when projects are completed. While the majority of one of these populations (Green Valley,

Encinitas and Carlsbad) is proposed for conservation, three others, all located within the City of Carlsbad, will be significantly reduced as a result of proposed development. Two of these populations currently contain nearly half of all individuals (about 3,000). After mitigation is implemented for proposed development projects, these populations will be reduced by about 50 percent and will be scattered over four parcels of open space containing fewer than 20 ha (50 ac). A 20 ha (50 ac) parcel is not likely to insure long-term conservation of *Arctostaphylos glandulosa* ssp. *crassifolia*. Additionally, the majority of the surviving individuals will be situated within 60 m (200 ft) of development and will likely be adversely affected by edge effects (Roberts 1993, City of Carlsbad and Fieldstone/La Costa Associates 1994, OGDEN 1995a). Therefore the Service finds that the claim that 82 percent of this taxon is proposed for conservation and preservation is not supported by available data. The best available data indicate that while about 80 percent of the *A. glandulosa* ssp. *crassifolia* populations are within dedicated open space, parks, or preserved areas (about 30 percent of the total San Diego County populations are within the Multiple Species Conservation Program (MSCP) preserve area), only about 55 percent of the total populations are preserved when edge effects and configuration of preserved areas are considered.

Issue 5: Two commenters stated that these taxa do not warrant listing because existing regulatory mechanisms provided by the California Environmental Quality Act (CEQA), County and City of San Diego Resource Protection Ordinances (RPO's), and multispecies programs including the State Natural Communities Conservation Plan (NCCP), and local MSCP, Multiple Habitat Conservation Plan (MHCP), and the Carlsbad Habitat Management Plan (HMP) provide adequate protection.

Service Response: Although the County and City of San Diego adopted RPO's in 1991, many of the populations of these four taxa occur outside the jurisdiction of these ordinances. For example, none of the major populations of *Arctostaphylos glandulosa* ssp. *crassifolia* are within the City of San Diego or on lands under County jurisdiction. Currently, the Service is aware of 10 development projects that have recently been approved or proposed that may eliminate nearly 50 percent of the remaining *Arctostaphylos glandulosa* ssp. *crassifolia*. This rate of decline is consistent with historical losses incurred over the last decade. As indicated by the commentor, many RPO's protect steep slopes. In addition, RPO's also apply to all biologically sensitive lands, which are defined to include those lands that support sensitive vegetation (San Diego Municipal Code § 101.0462). The ordinance further states that biologically sensitive lands shall be preserved in their natural state and that any encroachment must be minimal and must not adversely impact any rare, threatened or endangered species. This presumably would include any sites containing populations of the species listed herein.

The Service acknowledges that the NCCP, MSCP, MHCP, and HMP were not adequately discussed in the proposed rule. Most of these programs were in the early development stage at the time the rule was developed. However, the Service has both monitored and actively participated in coordinating the development of these programs as they have matured. The MSCP in southern coastal San Diego County has proceeded to a significant level. As a result of these planning efforts, one taxon (*Dudleya blochmaniae* ssp. *brevifolia*) originally proposed as endangered with the four subject taxa is being withdrawn (see separate concurrent Federal Register notice), while another (*Baccharis vanessae*) is being finalized as threatened instead of endangered. The Service considers the mitigation proposed within the MSCP adequate for threats to *Baccharis vanessae* and *Arctostaphylos glandulosa* ssp. *crassifolia* within the MSCP subregion. However, both taxa have significant populations outside this planning area. While other programs may ultimately provide significant protection to the taxa considered herein, at their current planning stages, the degree of conservation afforded these taxa is uncertain and would not significantly alter the Service position. A detailed discussion regarding these programs and others has been incorporated into the final rule under Factor D (''The inadequacy of existing regulatory mechanisms''). *Verbesina dissita* does not occur in San Diego County and is not subject to the MSCP, MHCP, or the HMP planning efforts.

Issue 6: One commenter stated that while the Service asserted that State and local regulatory controls are inadequate to protect these plant taxa, the Service failed to demonstrate how Federal listing will provide further protection. The commenter noted that the Endangered Species Act provides no direct protection to listed plants on private lands. Specifically, the commenter discussed how Federal listing would not provide *Arctostaphylos glandulosa* ssp. *crassifolia*, which occurs primarily on private lands, additional protection in the two examples cited in the proposed rule.

Service Response: The Service is required to determine whether any species qualifies for listing as endangered or threatened based on a review of the five factors listed under Section 4 of the Act. The Service acknowledges that the level of protection provided for listed plant species is not equivalent to the protection accorded federally listed animal species. Impacts to listed plant species are addressed through consultation with other Federal agencies when a Federal action is involved. While Federal actions may be limited on private lands, some protection may be afforded through this process. For example, in autumn of 1993, the United States Army Corps of Engineers (Corps) initiated conferencing regarding the proposed impacts of a large-scale development project on a significant population of *Arctostaphylos glandulosa* ssp. *crassifolia*. The conferencing process resulted in improved preservation of that taxon.

When assessing a habitat conservation plan under section 10(a)(1)(B) of the Act, the Service must conduct an internal consultation pursuant to section 7 of the Act to determine whether approval of the plan will jeopardize any federally proposed or listed plant or animal species. Additionally, ''take'' of federally listed plant species is prohibited under Federal law in circumstances where a State law is violated, such as a violation of the provisions of CEQA or the California Endangered Species Act.

Federal listing also provides a significant degree of recognition by State and local agencies and private landowners which may result in increased protection. Survey requirements and conservation guidelines for listed and non-listed species differ considerably under the State Coastal Protection Act, CEQA, RPO's and other local conservation regulations. Frequently, unlisted rare species are inadequately surveyed or given inadequate protection under these processes.

Issue 7: One commenter claimed that listing these taxa would have a negative effect on current multispecies planning efforts.

Service Response: The Service is required to determine whether any species is endangered or threatened based on the applicability of the five

factors listed under Section 4(a)(1) of the Act. While the Service supports the intent of multispecies planning efforts to avoid or reduce the need for future listing actions within designated planning areas, significant populations of the four taxa discussed herein are outside approved or nearly completed multispecies conservation plan areas (MSCP), or not adequately protected within approved plans (i.e., *Verbesina dissita* within the Central Coastal subregion of Orange County). Two of the four taxa are considered covered species under the MSCP (*Arctostaphylos glandulosa* ssp. *crassifolia* and *Baccharis vanessae*). Future impacts to these taxa within the MSCP have been considered and are addressed through planned preservation or management for plan participants throughout the subregion (see Available Conservation Measures). Thus listing these three taxa will not have a negative effect on current planning efforts. *Chorizanthe orcuttiana* is extremely rare and not considered adequately conserved by the MSCP. Federal and State listing actions frequently drive multispecies planning efforts and offer guidance to these conservation efforts, many of which are voluntary. Well-designed multispecies conservation plans must consider a wide range of sensitive species and their habitats. The necessity for additional listings indicate that these goals have not yet been met as indicated in the discussion under Factor D.

Issue 8: One commenter thought that the Service should designate critical habitat for all four taxa included in this rule, stating that critical habitat designation would support the mapping efforts and recommendations of the City of San Diego's MSCP, and that critical habitat should include all remaining southern maritime chaparral. Commenters noted that the locations of most of these taxa are available to the public through environmental impact reports, rebutting the Service's argument that the designation of critical habitat was not prudent since this would increase the likelihood of vandalism (i.e., habitat destruction) by revealing precise locations.

Service Response: The Service acknowledges that available public environmental documentation has already disclosed the location of many populations of the four taxa. The Service finds that designation of critical habitat is not prudent because it would not be beneficial to any of these four taxa. Critical habitat is only applicable to actions that have a Federal nexus. Any Federal action that may affect a listed species or designated critical habitat is addressed through section 7 of the Act, which requires a Federal agency to consult with the Service to determine if the action is likely to jeopardize a species or result in destruction or adverse modification of critical habitat. Of the four taxa, only *Chorizanthe orcuttiana* (historically) and *Baccharis vanessae* occur on Federal lands, and none are associated with wetlands which receive protection under section 404 of the Clean Water Act. It is anticipated that few of the remaining populations will be affected by actions of Federal agencies.

Issue 9: The Service should consider economic effects in determining whether to list these taxa under the Endangered Species Act.

Service Response: In accordance with section 4(b)(1)(A) of the Act, and 50 CFR 424.11(b) of the implementation regulations, listing decisions are made solely on the basis of the best available scientific and commercial information, without reference to possible economic or other impacts of such a determination.

Issue 10: One commenter stated that collection is not a threat to any of the four taxa.

Service Response: As discussed under Factor B (''Overutilization for commercial, recreational, scientific or educational purposes''), *Chorizanthe orcuttiana* is threatened by overcollection because of limited population size, horticultural appeal, and the relative ease of access to remaining sites.

Issue 11: Two commenters requested that a qualified party perform scientific peer review to reconcile the status of Del Mar manzanita as a distinct subspecies, and one suggested that the Service reopen the comment period to facilitate this review.

Service Response: As discussed in the Background section, disagreements over the taxonomic status of this species between Wells, the primary expert on the species, and Knight, who once proposed that the subspecies was not distinct, have been resolved in peer-reviewed publications.

Summary of Factors Affecting the Species

Section 4 of the Endangered Species Act and regulations (50 CFR part 424) promulgated to implement the listing provisions of the Act set forth the procedures for adding species to the Federal lists. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1). The threats facing these four taxa are summarized in Table 1.

TABLE 1.—SUMMARY OF THREATS

	Trampling	Alien plants	Fire control	Develop. activity	Limited numbers
Arctostaphylos glandulosa ssp. *crassifolia*	X	X	X	X	.....
Baccharis vanessae	X	X	X	X	X
Chorizanthe orcuttiana	X	X	.....	X	X
Verbesina dissita	.....	.....	X	X	.....

These factors and their application to *Arctostaphylos glandulosa* Eastw. ssp. *crassifolia* (Jeps.) Wells (Del Mar manzanita), *Baccharis vanessae* Beauchamp (Encinitas baccharis), *Chorizanthe orcuttiana* Parry (Orcutt's spineflower), and *Verbesina dissita* Gray (big-leaved crown-beard) are as follows:

A. *The present or threatened destruction, modification, or curtailment of its habitat or range.* One of the four taxa herein (Chorizanthe orcuttiana) is restricted to the south-central coast of San Diego County, California. *Baccharis vanessae* extends inland 32 km (20 mi) and north to the Santa Margarita Mountains of northern San Diego County. *Arctostaphylos glandulosa* ssp. *crassifolia* extends from the south-central coast of San Diego County south into northwestern Baja California, Mexico. *Verbesina dissita* occurs in two disjunct populations, one in coastal southern Orange County and one along the coast in northwestern Baja California, Mexico. The most imminent threat facing all four taxa and their associated habitats is the ongoing and threatened destruction and modification of habitat by one or more of the following—urban development, agricultural development, recreational

activities, trampling, and fuel modification activities.

Arctostaphylos glandulosa ssp. *crassifolia* (Del Mar manzanita) is restricted to sandstone-derived soils along the south-central coast of San Diego County, extending south to Mesa el Descanseo 40 km (25 mi) south of the United States border, Baja California, Mexico. This taxon is restricted almost exclusively to southern maritime chaparral and is considered to be an indicator species for this plant community. Estimates indicate that between 82 and 93 percent of southern maritime chaparral vegetation in San Diego County has been lost as a result of urban and agricultural development (Oberbauer and Vanderwier 1991; OGDEN 1993; D. Hogan, *in litt.*, 1993). Between 1980 and 1990, the population of San Diego County increased by more than 600,000 people. Most of this increase occurred on or near the coast at sites historically occupied, in part, by southern maritime chaparral. About 140 to 180 ha (300 to 450 ac) (12 to 30 percent) of southern maritime chaparral is currently located within approved or proposed developments in San Diego County (RECON 1987, Roberts 1992, SEB 1993a; D. Hogan, *in litt.*, 1993; Gail Kobetich, USFWS, *in litt.*, 1993). Less than 30 percent of the remaining southern maritime chaparral is preserved in parks (e.g., Torrey Pines State Park) with long-term management for conservation.

While 25 of 26 populations of *Arctostaphylos glandulosa* ssp. *crassifolia* are still extant in part, the majority of these populations have been greatly reduced and significantly fragmented by urban and agricultural development, most of which has occurred since 1982. About a 50 percent decline in the number of stands and the number of individuals has occurred since 1982 (Roberts 1993, SEB 1993b). Of the remaining individuals, the majority are distributed in highly fragmented habitat along the margins of residential development.

Over 75 percent of *Arctostaphylos glandulosa* ssp. *crassifolia* in the United States occurs within 6 concentrations located in Carlsbad, Encinitas, Del Mar, and Torrey Pines State Park. Four of the six populations, located in Carlsbad and Encinitas, are threatened in part by approved or proposed development projects. These projects will result in the elimination of over 1,900 individuals (over 35 percent) of A. g. ssp. *crassifolia* that occurs within these 6 populations through direct impacts. Furthermore the additional loss of 1,000 individuals (20 percent) will likely result from indirect impacts such as fuel modification and edge effects (Roberts 1993, SEB 1993a). Several of the smaller populations of A. g. ssp. *crassifolia* in Encinitas, Carlsbad, Carmel Valley and on Carmel Mountain are also threatened by development and associated indirect impacts (Roberts 1992, SEB 1993b).

The status of *Arctostaphylos glandulosa* ssp. *crassifolia* and its habitat in extreme northwestern Baja California, Mexico, are not well documented. However, this species only extends some 40 km (25 mi) south of the United States border. This region represents one of the most severely impacted areas in Baja California. Many of the same factors (urban and agricultural development) that have affected the status of this taxon in the United States are also clearly having an impact south of the border (Oberbauer 1992).

Chorizanthe orcuttiana (Orcutt's spineflower) is restricted to exposed sandy soils at two sites in coastal south-central San Diego County. One site, located at Torrey Pines State Park, is protected. However, this population has not been seen since 1987 (T. Oberbauer, pers. comm., 1992). The only currently known population is within Oak Crest Park in Encinitas, and this population is threatened by proposed recreational facilities (see Factor D). The reduction of the southern maritime chaparral in the park will have a significant impact on the long-term viability of the only existing *C. orcuttiana* population. Estimates indicate that between 82 and 93 percent of southern maritime chaparral vegetation in San Diego County has been lost as a result of urban and agricultural development (Oberbauer and Vanderwier 1991; OGDEN 1993; D. Hogan, *in litt.*, 1993).

Baccharis vanessae (Encinitas baccharis) is associated with dense mixed chaparral and southern maritime chaparral. Fourteen populations (and one isolated individual) currently exist. Seven of these remaining populations are threatened by development projects. Five populations are in the Del Dios Highlands within the Rancho Cielo project area. Three of these are threatened by urban development and a golf course (CDFG 1992). Clearing vegetation in 1991 and 1992 and application of herbicides in 1993, in combination with a serious fire in 1990, may already have eliminated some of these plants. Two other populations near Lake Hodges have been identified as threatened by proposed developments (CDFG 1992) or inundation from a proposed water storage facility (OGDEN 1995b).

In the United States, *Verbesina dissita* (big-leaved crown-beard) is restricted to rugged coastal hillsides and canyons in southern maritime chaparral and, to a lesser extent, coastal sage scrub and mixed chaparral, along a 3.2 km (2 mi) stretch of coastline in Laguna Beach, Orange County. Although some populations extend into Aliso-Woods Regional Park, the majority of the remaining populations are on private land and these populations are threatened by residential development and fuel modification activities (CDFG 1992).

Residential development and fuel modification activities continue to incrementally impact the main Laguna Beach population of *Verbesina dissita* (CDFG 1992). At least four residences were built directly on *V. dissita* plants after its State-listing as a threatened species in 1989. Although the individual houses eliminated a relatively small number of plants, local ordinances require the creation of a fuel modification zone up to 46 m (150 ft) from the residence (Richard Drewberry, Laguna Beach Fire Department, pers. comm., 1991). Over 20 percent of *V. dissita* occurrences are within 46 m (150 ft) of residential development. If these ordinances are fully implemented, a significant portion of this species in the United States would be eliminated. In 1984, a fuel break was cut through one population on Temple Hill. The species normally persists in relatively dense brush, although it is known to respond favorably to some clearing and fires. The plants in the fuel break began to decline after four years (Fred Roberts, USFWS, pers. obs., 1992). In 1991, the City of Laguna Beach used goats to clear fuel breaks despite objections that the goats could potentially consume rare plant species (Dr. Peter Bowler, University of California, Irvine, pers. comm., 1992). The City of Laguna Beach has indicated that many areas containing dense brush adjacent to residential development will be cleared (R. Drewberry, pers. comm., 1991). These areas are occupied in part by *V. dissita*. One development completed in 1989 has placed irrigation and hydromulching over one population. *Verbesina dissita* is not expected to persist with overwatering and competition from *Atriplex semibaccata* (Australian saltbush), which is frequently used in landscaping along the borders of development (F. Roberts, pers. obs., 1992).

The remaining habitat of *Verbesina dissita* in the United States is relatively contiguous. However, several developments have been proposed that will reduce and further fragment this rare vegetation association. Only 20 percent of the habitat is preserved (i.e., in Aliso-Woods Canyon Regional Park).

The majority of *Verbesina dissita* populations occur south of the United States-Mexican border in coastal, northwestern Baja California, where it occurs in vegetation associations similar to those found in Laguna Beach, California. The status of *V. dissita* and its habitat in Mexico are not well documented. According to one prominent researcher, the distribution of *V. dissita* in Mexico is spotty (R. Moran, pers. comm., 1992). Over 20 populations are known between Punta Descanseo and San Telmo near Cabo Colonet (Roberts 1988). A survey of historic localities in 1988 between Punta el Descanseo and Punta Santo Tomas determined that over 25 percent of these localities had been urbanized or converted to agriculture. Four separate localities are known from Punta Bunda just south of Ensenada. However, three of these are threatened by changes in land use from relatively pristine conditions in 1987 to extensive clearing in addition to rural condominium development in 1990 (F. Roberts, memo to file, 1992). Many of the same factors threatening the species in the United States (i.e., urban and agricultural development) are threatening this species in Mexico as well (Oberbauer 1992).

B. *Overutilization for commercial, recreational, scientific, or educational purposes.* Some taxa have become vulnerable to collecting by curiosity seekers as a result of increased publicity following the publication of listing proposals. *Chorizanthe orcuttiana* is highly restricted and is vulnerable to over-collection because of its rarity. Some professional and amateur botanists are known to favor collection of rare species, either to have examples in their collection or because these specimens are valuable to trade with other institutions.

C. *Disease or predation.* Disease is not known to be a factor for any of the taxa. Although swollen galls on the stems of *Baccharis vanessae* indicate parasitism by a moth or butterfly (Beauchamp 1980), insect predation of the four taxa is not well understood.

D. *The inadequacy of existing regulatory mechanisms.* Existing regulatory mechanisms that may provide some protection for *Arctostaphylos glandulosa* ssp. *crassifolia, Baccharis vanessae, Chorizanthe orcuttiana,* and *Verbesina dissita* include—(1) the California Endangered Species Act (CESA); (2) the California Environmental Quality Act (CEQA); (3) the California Natural Community Conservation Planning Program (NCCP), which includes the San Diego Multiple Species Conservation Plan (MSCP), Multiple Habitat Conservation Plan (MHCP), and Carlsbad Habitat Management plan (HMP); (4) the Federal Endangered Species Act in those cases where these taxa occur in habitat occupied by other listed species; (5) conservation provisions under the Federal Clean Water Act; (6) land acquisition and management by Federal, State, or local agencies, or by private groups and organizations; and (7) local laws and regulations.

State Laws and Regulation:

Pursuant to the Native Plant Protection Act (chapter 10 section 1900 *et seq.* of the California Fish and Game Code) and California Endangered Species Act (chapter 1.5 section 2050 *et seq.* of the Fish and Game Code), the California Fish and Game Commission listed *Baccharis vanessae* as endangered in 1987 and *Chorizanthe orcuttiana* in 1979. *Verbesina dissita* was listed as threatened by the State of California in 1989. Although both statutes prohibit the ''take'' of State-listed plants (chapter 10 section 1908 and chapter 1.5 section 2080), some projects do not comply with State law. As an example, in 1992, *V. dissita* plants in Laguna Beach were removed without the State's knowledge (Ken Berg, CDFG, pers. comm., 1992).

Local lead agencies empowered to uphold and enforce the regulations of the CEQA have made determinations that have or will adversely affect these taxa and their southern maritime chaparral habitat. The CEQA requires that a project proponent publicly disclose the potential environmental impacts of proposed projects. The public agency with primary authority or jurisdiction over the project is designated as the lead agency, and is responsible for conducting a review of the project and consulting with other agencies concerned with resources affected by the project. Required biological surveys are often inadequate and project proponents may disregard the results of surveys if occurrences of sensitive species are viewed as a constraint on project design. Mitigation measures used to condition project approvals are often experimental and fail to adequately guarantee protection of sustainable populations of the taxa considered herein. CEQA decisions are also subject to overriding social and economic considerations.

To illustrate, the environmental documentation for a large-scale development project in Carlsbad did not include sufficient surveys for *Chorizanthe orcuttiana* or *Baccharis vanessae* (Pacific Southwest Biological Services 1990; Larry Sward, SEB, *in litt.*, 1993), although the only currently known population of *C. orcuttiana* occurs in Encinitas, less than 3.2 km (2 mi) distant, and one of the largest populations of *B. vanessae* occurs on an adjacent parcel. One of the largest populations of *Arctostaphylos glandulosa* ssp. *crassifolia* also occurs within this project site. Although impacts to this taxon were identified as significant under the CEQA, the adopted mitigation measures were considered to be insufficient (S. Lacy, *in litt.*, 1991). In another project within the City of Carlsbad, the elimination of a population of *A. g.* ssp. *crassifolia* was not considered to be a significant impact, even though the taxon was a Federal category 2 candidate for listing at the time (M.F. Ponseggi and Associates 1993). Impacts to category 2 candidates were considered significant under the CEQA prior to 1996 revisions in candidate policy that eliminated category 2 ranking (61 FR 7596; February 28, 1996).

Moreover, transplantation is frequently used to mitigate for the loss of rare plant species; however, it has yet to be demonstrated to provide for long-term viability of any of the four taxa. Several attempts at transplanting *Baccharis vanessae* and *Arctostaphylos glandulosa* ssp. *crassifolia* have been reported by Hall (1987). Attempts to transplant *B. vanessae* at Quail Botanical Garden and at San Dieguito County Park failed shortly after the monitoring period ended. Six years after individuals of *A. g.* ssp. *crassifolia* were transplanted at Quail Botanical Garden, 75 percent of the plants had died.

Regional Planning Efforts

In 1991, the State of California established the NCCP program to address conservation needs throughout the State. The focus of current planning programs is the coastal sage scrub community in southern California, although other vegetation communities are being addressed in an ecosystem-level approach. Southern maritime chaparral and the four taxa are currently being considered under the MSCP, MHCP, and the Orange County Central Coastal NCCP programs. The MHCP, which will include the Carlsbad HMP program, is still in the early developmental phase and thus it is uncertain to what degree it will be successful in providing protection for these taxa.

The NCCP for the Central and Coastal Subregion of Orange County was approved in July of 1996. Only one of the four taxa (*Verbesina dissita*) occurs within the Central/Coastal NCCP. While the entire population of this species in

the United States is within this subregion, only about 10 percent of the species'' distribution is protected by the Central/Coastal Plan. The species is not adequately conserved, nor is it considered a ''covered species'' under the plan. Covered species are those species that have been adequately considered in terms of long-term preservation within a Habitat Conservation Planning Area or NCCP subregion. Under an agreement with the participants, CDFG, and the Service, future potential impacts for covered species are considered adequately addressed through proposed preservation, mitigation, and management.

Since the publication of the proposed rule, the MSCP, a regional planning effort in southwestern San Diego County, has been finalized and submitted to the Service as part of an application for a section 10(a)(1)(B) incidental take permit for 85 species, including *Arctostaphylos glandulosa* ssp.0 *crassifolia* and *Baccharis vanessae.* The Service and the City of San Diego have jointly prepared a *Recirculated Environmental Impact Report/Environmental Impact Statement, Issuance of Take Authorizations for Threatened and Endangered Species due to Urban Growth within the Multiple Species Conservation Program (MSCP) Planning Area.* This document, released on August 30, 1996, for a 45-day public review period, assesses the effects of land-use decisions that will be made by local jurisdictions to implement the plan and the effects of the proposed issuance of the incidental take permit on the 85 species. A decision on the permit issuance is expected in late 1996.

The MSCP will, upon approval, set aside preservation areas and provide monitoring and management for the 85 ''covered species'' addressed in the permit application, including *Arctostaphylos glandulosa* ssp. *crassifolia* and *Baccharis vanessae.* ''Covered species'' are taxa that will be adequately conserved by the plan's proposed preservation and management. About 30 percent of the *A. g.* ssp. *crassifolia* population (without consideration to edge effect) is protected within the MSCP (about 90 percent of the species' total populations are within the subregion) and about 45 percent of *B. vanessae* populations are protected within the MSCP (about 70 percent of the total populations are within the subregion). While all threats have not been eliminated for these two taxa within the subregion, the Service believes that future potential impacts will be adequately addressed by management incorporated into the final MSCP agreement. Project proponents in areas outside the MSCP subregion will be required to coordinate with the Service on these taxa where applicable.

Federal Laws and Regulations

The Endangered Species Act may already afford protection to candidate or other sensitive species if they co-exist with species already listed as threatened or endangered under the Act. Although the coastal California gnatcatcher (*Polioptila californica californica*) is listed as threatened under the Act and overlaps with the range of the taxa considered herein, the coastal California gnatcatcher primarily utilizes a different habitat (coastal sage scrub). Additionally, under provisions of section 10(a) of the Act, the Service may permit the incidental ''take'' of the gnatcatcher during the course of an otherwise legal activity provided that the taking will not appreciably reduce the likelihood of its survival and recovery in the wild. Projects developed with authorization for take of the coastal California gnatcatcher may, however, contribute to the decline of *Arctostaphylos glandulosa* ssp. *crassifolia, Baccharis vanessae* and *Chorizanthe orcuttiana* in areas where the project area includes both coastal sage scrub and southern maritime chaparral.

Some protection has been afforded to these taxa through section 404 of the Clean Water Act (G. Kobetich, *in litt.,* 1993). However, since the majority of these taxa occur in upland habitat or in isolated and fragmented parcels, it is unlikely that actions affecting the taxa will require section 404 permits.

Land Acquisition and Management

Land acquisition and management by State or local agencies or by private groups and organizations have contributed to the protection of some localities containing the taxa included in this rule. However, as discussed below, these efforts are inadequate to assure the long-term survival of these four taxa. For example, Torrey Pines State Park and Crest Canyon Preserve (Del Mar) contain significant populations of *Arctostaphylos glandulosa* ssp. *crassifolia.* While Torrey Pines State Park is managed for long-term preservation of biological resources, the populations within the park contain less than 20 percent of the remaining *A. g.* ssp. *crassifolia* individuals. The populations of this taxon in Crest Canyon Preserve Park are affected by trampling associated with recreational activities and edge effects (see Factor E). A small population of *A. g.* ssp. *crassifolia* located within San Dieguito County Park is also threatened by edge effects and trampling from recreational activities.

Three of the species considered within this rule (*Arctostaphylos glandulosa* ssp. *crassifolia, Baccharis vanessae,* and *Chorizanthe orcuttiana*) occur within Oak Crest Park in Encinitas. While this park is under public ownership and management, these plants are threatened by the construction of recreational facilities, invasive exotics, and trampling (see Factors A and E).

A single population of *Baccharis vanessae* is known from the Cleveland National Forest in the Santa Margarita Mountains (S. Boyd, Rancho Santa Ana Botanical Garden, *in litt.,* 1992). While this population is protected in part because it is isolated, it represents less than 10 percent of the known populations of this species. In Orange County, *Verbesina dissita* extends into Aliso-Woods Canyons Regional Park. However, this park encompasses less than 10 percent of the known populations of the species. Additionally, while this county regional park is, in part, managed for biological conservation, *V. dissita* is threatened by fuel modification (i.e., thinning, mechanical clearing, and irrigation) and exotic vegetation replacement at the park boundary.

These plant taxa also occur in ''dedicated'' open space frequently in association with development projects. These areas are often specifically set aside for conservation as required by local and county project approvals and/or the CEQA, and are managed by private organizations, individuals, corporations, or local jurisdictions. However, open space dedications do not incorporate the principles of conservation biology. Many are inadequately configured, or are too small for the long-term preservation of these taxa (see Factor E). County open space designations within General Development Plans are subject to amendments and, therefore, cannot be considered as permanent conservation.

Local Laws, Regulations, and Ordinances

The four taxa in this rule have been identified as sensitive under various local laws, regulations and ordinances. However, development projects continue to be approved and implemented with designs that do not preserve populations or habitat for the taxa considered herein. Currently, the Service is aware of 10 approved or proposed development projects that will directly or indirectly impact about 3,000

individuals of *Arctostaphylos glandulosa* ssp. *crassifolia.* While these projects have been or currently are subject to review under existing local regulatory mechanisms and conservation plans, this taxon is still declining rapidly. Management and recovery become increasingly difficult as options for preservation are reduced.

Existing local land-use regulations have failed to protect these taxa as exemplified by Oak Crest Park in Encinitas. Although a portion of the park was originally set aside for conservation purposes by the County of San Diego (D. Hogan, *in litt.,* 1991; T. Oberbauer, pers. comm., 1992), recreational development has eliminated southern maritime chaparral habitat and individuals of *Arctostaphylos glandulosa* ssp. *crassifolia, Baccharis vanessae,* and *Chorizanthe orcuttiana.* One area recently developed included a natural preserve area set aside under an agreement between the City and the California Coastal Commission. Current recreational development plans for Oak Crest Park, including the construction of a community center, swimming pool and numerous walking paths, will impact two of these taxa (*A. g.* ssp. *crassifolia* and *B. vanessae*). The proposed development will reduce the *B. vanessae* population and the extent of southern maritime chaparral within the park by approximately one-third (David Wigginton, City of Encinitas Community Services, pers. comm., 1992).

Another example demonstrating how existing regulatory mechanisms are inadequate is provided by a project in the City of Carlsbad that was originally approved circa 1980. The project area contained the northernmost known population of *Arctostaphylos glandulosa* ssp. *crassifolia* and a significant stand of southern maritime chaparral. When a city official was approached by the project proponent in 1992, the city informed the proponent that the existing CEQA documentation was inadequate and that additional biological surveys would be required. Despite this finding, the proponent was able to obtain grading permits to clear the land without additional documentation (Terri Stewart, CDFG, pers. comm., 1992).

Several development projects have proceeded without adequate surveys for *Chorizanthe orcuttiana* (City of Carlsbad and Fieldstone/La Costa Associates 1994). *Arctostaphylos glandulosa* ssp. *crassifolia* has been considered in the majority of these plans; however projects have recently been proposed and approved that have or will directly or indirectly eliminate nearly half of the population within these planning areas (SEB 1993a, 1993b). Because *A. g.* ssp. *crassifolia* has already declined by about 50 percent over the last decade, these additional significant losses will contribute to the further decline of this taxon and may affect its recovery (Roberts 1993; SEB 1993b; G. Kobetich, *in litt.,* 1993). Although the only extant population of *C. orcuttiana* is on public land within the jurisdiction of the MHCP, no protection measures have been developed or implemented for this population. Several important populations of *Baccharis vanessae* are threatened by current project proposals that will reduce the effectiveness of the MHCP, when developed, to adequately stabilize populations within the subregion (OGDEN 1995a; D. Hogan, *in litt.,* 1991; D. Wigginton, pers. comm., 1992). The additional recognition that results from listing is expected to generate additional efforts in providing for the long-term preservation of these four taxa.

Laws and Regulation in Mexico

The range of *Arctostaphylos glandulosa* ssp. *crassifolia* and *Verbesina dissita* continues south along the Pacific coast into northwestern Baja California, Mexico. Mexico has laws that presumably provide protection to rare plants; however, enforcement of these laws is lacking (USFWS 1992b).

In summary, although most of these taxa are receiving at least some protection through existing regulatory mechanisms, threats continue to adversely affect the taxa, as indicated by their declining status.

E. *Other natural or manmade factors affecting their continued existence.* At least two of the taxa (*Baccharis vanessae* and *Chorizanthe orcuttiana*) may be threatened by a risk of extinction from naturally occurring events because of their restricted distribution and small population size. Genetic viability can be reduced in small populations, making them less adaptable to changes in the environment. The potential for extirpation by virtue of their small population sizes can be exacerbated by natural causes such as drought or fire. For example, the impact of fire on *Baccharis vanessae* is not fully understood, yet a 1,200 ha (3,000 ac) fire in the Del Dios highlands burned four of the known populations in September 1990 (CDFG 1992, Los Angeles Times 1992). Many populations are now in close proximity to residential development, and are threatened by edge effects including fuel modification activities, fire suppression, the invasion of exotic plant species, and increased human activities associated with nearby urbanization. Additionally, unidentified pollinators or seed-dispersal agents for these taxa may also be impacted by development.

Habitat fragmentation and isolation, in addition to fuel modification, threaten the taxa in areas adjacent to residential development. For example, nearly 15 percent of extant *Arctostaphylos glandulosa* ssp. *crassifolia* occurs in small, fragmented, and isolated parcels of open space (Roberts 1993). Of the six largest populations of this taxon, 20 percent of the individuals are within 60 m (200 ft) of existing development and are threatened by edge effects (Roberts 1993, SEB 1993a). This is exemplified by Crest Canyon Preserve, where nearly 50 percent of the approximately 1,000 individuals of *A. g.* ssp. *crassifolia* are within 60 m (200 ft) of development. *Arctostaphylos glandulosa* ssp. *crassifolia* is also threatened by trampling where trails have been cut through populations by recreationalists and farm workers (Hogan 1990; CDFG 1992; F. Roberts and E. Berryman, USFWS, pers. obs.).

Conflicts between fire management and preservation arise when insufficient buffers exist between sensitive biological resources and residential dwellings. A recent example includes clearing of about 1 ha (2 ac) of southern maritime chaparral adjacent to a new residential development in Carlsbad in June 1992.

Baccharis vanessae is limited to small numbers, comprising only 14 extant populations containing about 2,000 individuals. No population is known to have over 300 individuals and 5 of these populations have fewer than 6 individuals. One individual has been discovered on the western slopes of Carmel Mountain.

Chorizanthe orcuttiana, known from a single locality, is the most vulnerable of the four taxa. This species is threatened by trampling by farm workers and recreationalists because of its small size and its preference for open areas, which tend to attract foot traffic through otherwise dense chaparral vegetation (F. Roberts and E. Berryman, pers. obs.). The only known site could be eliminated in a single event if a particularly large number of people were to walk through and trample the population. Exotic grass and weed species are also threatening the population.

All four taxa are potentially threatened by the interruption of the natural fire cycle. Fragmentation has rendered individual populations more susceptible to fire events that may either

occur too frequently or be suppressed too long to maintain a healthy southern maritime chaparral habitat.

The Service has carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by these four taxa in determining to make this rule final. Based on this evaluation, the preferred action is to list *Arctostaphylos glandulosa* ssp. *crassifolia* and *Chorizanthe orcuttiana* as endangered. These taxa are in danger of extinction throughout all or a significant portion of their ranges due to habitat alteration and destruction resulting from urban, recreational and agricultural development; fuel modification activities; trampling by farm workers and recreational activities; inadequacy of existing regulatory mechanisms; naturally occuring events due to limited populations; and competition from exotic plant species. For the reasons discussed below, the Service finds that *Verbesina dissita* and *Baccharis vanessae* are likely to become endangered within the foreseeable future throughout all or a significant portion of their range. Although *V. dissita* is extremely threatened in the United States by development and fuel modification activities, the status of this species in Baja California, Mexico, is considerably better due to a larger number of extant populations. However, it is still threatened by similar activities in Mexico. Therefore the preferred action is to list *V. dissita* as threatened. While nearly half of the known *B. vanessae* populations continue to be at risk from urban development, inundation from a proposed water storage facility, and fire management methods, the species is not in immediate danger of extinction. The Service therefore revises the preferred action for *B. vanessae* from listing as endangered in the original proposed regulation to listing as threatened in this final rule. In addition, the MSCP in San Diego County will offer significant management and preservation for about half of the populations upon its authorization. Critical habitat is not being proposed for these taxa for the reasons discussed below.

Critical Habitat

Critical habitat, is defined in section 3 of the Act, as: (i) The specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management considerations or protection; and (ii) specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. ''Conservation'' means the use of all methods and procedures needed to bring the species to the point at which listing under the Act is no longer necessary.

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time the species is determined to be endangered or threatened. The Service finds that designation of critical habitat is not prudent for the taxa discussed in this rule at this time. Service regulations (50 CFR 424.12(a)(1)) state that designation of critical habitat is not prudent when one or both of the following situations exist—(1) the species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of such threat to the species; or (2) such designation of critical habitat would not be beneficial to the species.

As discussed under Factor B, Chorizanthe *orcuttiana* is particularly threatened by taking, specifically overcollecting, an activity difficult to regulate and enforce. Taking is only regulated by the Act with respect to plants in cases of (1) removal and reduction to possession of federally listed plants from lands under Federal jurisdiction, or their malicious damage or destruction on such lands; and (2) removal, cutting, digging-up, or damaging or destroying in knowing violation of any State law or regulation, including State criminal trespass law. The publication of precise maps and descriptions of critical habitat in the Federal Register would make these plants more vulnerable to incidents of collection or vandalism and, therefore, could contribute to the decline of this species.

Critical habitat designation provides protection only on Federal lands or on private lands when there is Federal involvement through authorization or funding of, or participation in, a project or activity. Of the taxa discussed herein, only one population of *Baccharis vanessae* is known to occur on Federal lands. All Federal and state agencies and local planning agencies involved have been notified of the location and importance of protecting the habitat of these taxa. Protection of their habitat will be addressed through the recovery process and through the section 7 consultation process. Section 7(a)(2) of the Act requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried out by such agency, does not jeopardize the continued existence of a federally listed species, or does not destroy or adversely modify designated critical habitat. The taxa in this rule are all confined to small geographic areas and each population is composed of so few individuals that the determinations for jeopardy and adverse modification would be similar. Therefore, designation of critical habitat provides no additional benefit beyond those that these taxa would receive by virtue of their listing as endangered or threatened species and likely would increase the degree of threat from vandalism, collecting, or other human activities. The Service finds that designation of critical habitat is not prudent for these taxa at this time.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Endangered Species Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain activities. Recognition through listing encourages and results in conservation actions by Federal, State, and local agencies, private organizations, and individuals. The Act provides for possible land acquisition from willing sellers and cooperation with the States and requires that recovery actions be carried out for all listed species. The protection required of Federal agencies and the prohibitions against certain activities involving listed plants are discussed, in part, below.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service.

Although only one of the four taxa (*Baccharis vanessae* at the Olivenhein Water Storage Facility) is known to be directly affected by activities permitted under section 404 of the Clean Water Act, effects of actions that include direct and indirect impacts that are interrelated or interdependent with the taxa under consideration may require a permit under section 404 of the Clean Water Act. Additionally, two of the taxa (*Arctostaphylos glandulosa* ssp. *crassifolia* and *B. vanessae*) are known to occur in areas where highway projects, which may involve Federal funding and the Federal Highways Administration, have been proposed. At least one taxon (*B. vanessae*) occurs on Federal land, within the Cleveland National Forest and within 1 km (0.6 mi) of Camp Pendelton Marine Base. New populations of these taxa could be discovered at Miramar Naval Air Station, Point Loma Naval Reserve, and Camp Pendelton Marine Base. These Federal nexuses would require initiation of section 7 consultation on actions that may affect the taxa.

Two of these species, *Arctostaphylos glandulosa* ssp. *crassifolia* and *Baccharis vanessae,* are considered covered species under the MSCP. These species will receive benefits from the plan upon its approval. These benefits include—(1) preservation of the majority of populations within the subregion including two major populations of *A. g.* ssp. *crassifolia* and one and a half major populations of *B. vanessae,* (2) management plans that will address impacts from fuel management and close proximity of existing and proposed development, and (3) monitoring of the status of these populations. Some populations within this subregion will be eliminated or reduced, but it has been determined that the populations preserved under the plan will be adequate to stabilize the status of these taxa within the MSCP planning area.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to all endangered or threatened plants. All prohibitions of section 9(a)(2) of the Act, implemented by 50 CFR 17.61 (endangered plants) or 17.71 (threatened plants), apply. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export, transport in interstate or foreign commerce in the course of a commercial activity, sell or offer for sale in interstate or foreign commerce, or remove and reduce the species to possession from areas under Federal jurisdiction. In addition, for plants listed as endangered, the Act prohibits the malicious damage or destruction on any area under Federal jurisdiction and the removal, cutting, digging up, or damaging or destroying of such endangered plants in knowing violation of any State law or regulation, including State criminal trespass law. Section 4(d) of the Act allows for the provision of such protection to threatened species through regulation. This protection may apply to *Baccharis vanessae* and *Verbesina dissita* in the future if regulations are promulgated. Seeds from cultivated specimens of threatened plant species are exempt from these prohibitions provided that their containers are marked ''Of Cultivated Origin''. Certain exceptions to the prohibitions apply to agents of the Service and State conservation agencies.

The Act and 50 CFR 17.62, 17.63, and 17.72 also provide for the issuance of permits to carry out otherwise prohibited activities involving endangered or threatened species under certain circumstances. Such permits are available for scientific purposes and to enhance the propagation or survival of the species. For threatened plants, permits are also available for botanical or horticultural exhibition, educational purposes, or special purposes consistent with the purpose of the Act. It is anticipated that few trade permits would ever be sought or issued because none of the four taxa are common in cultivation or in the wild.

It is the policy of the Service, published in the Federal Register on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of this listing on proposed and ongoing activities within the species' range. One of these four taxa (*Baccharis vanessae*) is known to occur on lands under the jurisdiction of the U.S. Forest Service and populations of the taxa may potentially be discovered on lands under the jurisdiction of the Department of Defense (Navy). Collection, damage or destruction of any of these species on Federal lands is prohibited, although in appropriate cases a Federal endangered species permit may be issued to allow collection. Such activities on non-Federal lands would constitute a violation of section 9 if conducted in knowing violation of State law or regulations or in violation of State criminal trespass law. The Service is not aware of any otherwise lawful activities being conducted or proposed by the public that will be affected by this listing and result in a violation of section 9.

Questions regarding whether specific activities will constitute a violation of section 9 should be directed to the Field Supervisor of the Service's Carlsbad Field Office (see **ADDRESSES** section). Requests for copies of the regulations concerning listed plants and general inquiries regarding prohibitions and permits may be addressed to the U.S. Fish and Wildlife Service, Ecological Services, Endangered Species Permits, 911 N.E. 11th Avenue, Portland, Oregon 97232-4181 (telephone 503/231-2063; facsimile 503/231-6243).

National Environmental Policy Act

The Fish and Wildlife Service has determined that Environmental Assessments and Environmental Impact Statements, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act of 1973, as amended. A notice outlining the Service's reasons for this determination was published in the Federal Register on October 25, 1983 (48 FR 49244).

References Cited

A complete list of all references cited herein is available upon request from the Carlsbad Field Office (see **ADDRESSES** section).

Author

The primary author of this final rule is Fred M. Roberts, Jr., Carlsbad Field Office (see **ADDRESSES** section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, and Transportation.

Regulation Promulgation

Accordingly, part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, is amended as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. Section 17.12(h) is amended by adding the following, in alphabetical order under FLOWERING PLANTS, to the List of Endangered and Threatened Plants, to read as follows:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Species		Historic range	Family	Status	When listed	Critical habitat	Special rules
Scientific name	Common name						
FLOWERING PLANTS:							
*	*	*	*	*	*	*	
Arctostaphylos glandulosa ssp. crassifolia.	Del Mar manzanita ...	U.S.A. (CA), Mexico	Ericaceae	E	589	NA	NA
*	*	*	*	*	*	*	
Baccharis vanessae	Encinitas baccharis	U.S.A. (CA)	Asteraceae	T	589	NA	NA
*	*	*	*	*	*	*	
Chorizanthe orcuttiana.	Orcutt's spineflower	U.S.A. (CA)	Polygonaceae	E	589	NA	NA
*	*	*	*	*	*	*	
Verbesina dissita	Big-leaved crown-beard.	U.S.A. (CA), Mexico	Asteraceae	T	589	NA	NA
*	*	*	*	*	*	*	

Dated: September 27, 1996.

John G. Rogers,

Acting Director, Fish and Wildlife Service.

[FR Doc. 96–25462 Filed 10–4–96; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 951116270–5308–02; I.D. 092696B]

Fisheries of the Northeastern United States; Summer Flounder Fishery; Commercial Quota Harvested for Massachusetts

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Commercial quota harvest.

SUMMARY: NMFS issues this notification announcing that the summer flounder commercial quota available to the Commonwealth of Massachusetts has been harvested. Vessels issued a commercial Federal fisheries permit for the summer flounder fishery may not land summer flounder in Massachusetts for the remainder of calendar year 1996, unless additional quota becomes available through a transfer. Regulations governing the summer flounder fishery require publication of this notification to advise the Commonwealth of Massachusetts that the quota has been harvested and to advise vessel and dealer permit holders that no commercial quota is available for landing summer flounder in Massachusetts.

EFFECTIVE DATE: October 2, 1996 through December 31, 1996.

FOR FURTHER INFORMATION CONTACT: Lucy Helvenston, 508–281–9347.

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found at 50 CFR part 648. The regulations require annual specification of a commercial quota that is apportioned among the states from North Carolina through Maine. The process to set the annual commercial quota and the percent allocated to each state are described in § 648.100.

The total commercial quota for summer flounder for the 1996 calendar year is set equal to 11,111,298 lb (5,040,000 kg) (January 4, 1996, 61 FR 291). The percent allocated to vessels landing summer flounder in Massachusetts is 6.82046 percent, or 757,841 lb (343,751 kg).

Section 648.100(d)(2) provides that any overages of the commercial quota landed in any state will be deducted from that state's annual quota for the following year. In the calendar year 1995, a total of 1,127,995 lb (511,650 kg) were landed in Massachusetts. The amount allocated for Massachusetts landings in 1995 was 1,122,246 lb (509,042 kg), creating a 5,749 lb (2,608 kg) overage that was deducted from the amount allocated for landings in that state during 1996 (April 5, 1996, 61 FR 15199). The resulting quota for Massachusetts is 752,092 lb (341,143 kg).

Section 625.101(b) requires the Regional Administrator, Northeast Region (Regional Administrator) to monitor state commercial quotas and to determine when a state commercial quota is harvested. The Regional Administrator is further required to publish a notification in the Federal Register advising a state and notifying Federal vessel and dealer permit holders that, effective upon a specific date, the state's commercial quota has been harvested and no commercial quota is available for landing summer flounder in that state. Because the available information indicates that the Commonwealth of Massachusetts has attained its quota for 1996, the Regional Administrator has determined that based on dealer reports and other available information, the State's commercial quota has been harvested.

The regulations at § 648.4(b) provide that Federal permit holders agree as a condition of the permit not to land summer flounder in any state that the Regional Administrator has determined no longer has commercial quota available. Therefore, effective 0001 hours October 2, 1996 further landings of summer flounder in Massachusetts by vessels holding commercial Federal fisheries permits are prohibited for the remainder of the 1996 calendar year, unless additional quota becomes available through a transfer and is announced in the Federal Register. Federally permitted dealers are also advised that they may not purchase summer flounder from federally permitted vessels that land in Massachusetts for the remainder of the

calendar year, or until additional quota becomes available, effective on October 2, 1996.

Classification

This action is required by 50 CFR part 648 and is exempt from review under E.O. 12286.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 2, 1996.

Bruce Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 96–25642 Filed 10–2–96; 4:30 pm]

BILLING CODE 3510–22–F

50 CFR Part 679

[Docket No. 960129018–6018–01; I.D. 093096D]

Fisheries of the Exclusive Economic Zone Off Alaska; Recordkeeping and Reporting Requirements in the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of change in recordkeeping and reporting requirements.

SUMMARY: NMFS has determined that Daily Production Reports (DPRs) must be submitted by processor vessels using trawl gear that catch or receive rockfish species of the genera *Sebastes* and *Sebastolobus* and shoreside processing facilities that receive rockfish species of the genera *Sebastes* and *Sebastolobus* from vessels using trawl gear in the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the total allowable catches (TACs) for rockfish species and species groups in the GOA.

EFFECTIVE DATE: From 1200 hrs, Alaska local time (A.l.t.), October 1, 1996, through the duration of the 1996 directed rockfish fisheries in the GOA or until the Director, Alaska Region, NMFS determines the supplementary reporting requirements are no longer necessary or until directed fishing for trawl gear is closed. This determination will be published in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Andrew N. Smoker, 907-586-7228.

SUPPLEMENTARY INFORMATION: The groundfish fishery in the Gulf of Alaska exclusive economic zone is managed by NMFS according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at subpart H of 50 CFR part 600 and 50 CFR part 679.

Pursuant to § 679.5(j) the Regional Director is requiring processor vessels using trawl gear that catch or receive rockfish species of the genera *Sebastes* and *Sebastolobus* and shoreside processing facilities that receive rockfish species of the genera *Sebastes* and *Sebastolobus* from vessels using trawl gear as defined at § 679.2 in the GOA to submit DPRs in addition to weekly processor reports.

The remainder of the TAC for rockfish species of the genera *Sebastes* and *Sebastolobus* under § 679.20(a)(2) will become available for directed fishing 1200 hrs, A.l.t., October 1, 1996, as the fourth quarterly allowance of Pacific halibut prohibited species catch limits for trawl gear becomes available. These rockfish amounts are expected to be rapidly harvested, and the Regional Director has determined that requiring DPRs is necessary to avoid exceeding TAC.

DPRs must include all information required by § 679.5(j)(4) for groundfish harvested from the applicable reporting areas. Processors must submit the required information on the ''Alaska Groundfish Processor Daily Production Report'' form that was distributed to participants in the groundfish fishery with their 1996 Federal fisheries permit. The form also may be obtained from the Regional Director by calling Mary Furuness at 907–586–7228. Processors must transmit completed DPRs to the Regional Director by facsimile transmission to number 907–586-7131, no later than 12 hours after the end of the day the groundfish was processed.

If and when the Regional Director determines that these reports are no longer necessary, he may terminate the requirement. Criteria used to assess the need for the reports include the stability of effort and harvest rates in the fishery, and remaining amounts.

The Assistant Administrator for Fisheries, NOAA, has found that reasons justifying promulgation of this action also make it impracticable and contrary to the public interest to provide notice and opportunity for prior comment or to delay for 30 days its effective date. Intense fishing effort without DPRs could result in industry's exceeding these allocations.

Classification

This action is taken under 50 CFR 679.20 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 1, 1996.

Bruce Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 96–25587 Filed 10–02–96; 9:33 am]

BILLING CODE 3510–22–F

50 CFR Part 679

[Docket No. 960129019–6019–01; I.D. 100196B]

Fisheries of the Exclusive Economic Zone Off Alaska; Yellowfin Sole by Vessels Using Trawl Gear in the Bering Sea and Aleutian Islands

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure.

SUMMARY: NMFS is closing the directed fishery for yellowfin sole by vessels using trawl gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 1996 bycatch mortality allowance of Pacific halibut apportioned to the trawl yellowfin sole fishery in the BSAI.

EFFECTIVE DATE: 1200 hours, Alaska local time (A.l.t.), October 2, 1996, until 2400 hours, A.l.t., December 31, 1996.

FOR FURTHER INFORMATION CONTACT: Mary Furuness, 907–586-7228.

SUPPLEMENTARY INFORMATION: The groundfish fishery in the BSAI exclusive economic zone is managed by NMFS according to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 1996 bycatch mortality allowance of Pacific halibut for the BSAI trawl yellowfin sole fishery, which is defined at § 679.21(e)(3)(iv)(B)(1), was established by the Final 1996 Harvest Specifications of Groundfish (61 FR 4311, February 5, 1996) as 820 metric tons.

The Director, Alaska Region, NMFS, has determined, in accordance with § 679.21(e)(7)(iv), that the 1996 bycatch mortality allowance of Pacific halibut apportioned to the trawl yellowfin sole fishery in the BSAI has been caught. Therefore, NMFS is prohibiting directed fishing for yellowfin sole by vessels using trawl gear in the BSAI.

Maximum retainable bycatch amounts for applicable gear types may be found in the regulations at § 679.20(e).

Classification

This action is taken under 50 CFR 679.21 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 2, 1996.

Bruce Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 96–25641 Filed 10–2–96; 4:30 pm]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 61, No. 195
Monday, October 7, 1996

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 AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 91

[Docket No. 96–054–1]

Ports Designated for the Exportation of Animals; Georgia

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the ''Inspection and Handling of Livestock for Exportation'' regulations by adding Atlanta Hartsfield International Airport, Atlanta, GA, as a port of embarkation from which animals may be exported from the United States and by adding three Georgia facilities, the Atlanta Equine Complex in Atlanta, Tumbleweed Farm in Mableton, and Southern Cross Ranch in Madison, to the list of approved export inspection facilities. These proposed actions would update the regulations by adding a port and three inspection facilities through which animals may be processed for export.

DATES: Consideration will be given only to comments received on or before December 6, 1996.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 96–054–1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 96–054–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Andrea Morgan, Senior Staff Veterinarian, Import/Export Animals, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231, (301) 734–8354.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 91, ''Inspection and Handling of Livestock for Exportation'' (referred to below as the regulations), prescribe conditions for exporting animals from the United States. The regulations state, among other things, that all animals, except animals being exported by land to Canada or Mexico, must be exported through designated ports of embarkation.

Section 91.14(a) contains a list of designated ports of embarkation and export inspection facilities. To receive designation as a port of embarkation, a port must have export inspection facilities available for the inspection, holding, feeding, and watering of animals prior to exportation to ensure that the animals meet certain requirements specified in the regulations. To receive approval as an export inspection facility, the regulations provide that a facility must meet specified standards in § 91.14(c) concerning materials, size, inspection implements, cleaning and disinfection, feed and water, access, testing and treatment, location, disposal of animal wastes, lighting, office and restroom facilities, and walkways.

We believe that the Atlanta Equine Complex, 1270 Woolman Place, Atlanta, GA 30354, (404) 767–1700; Tumbleweed Farm, 1677 Buckner Road, Mableton, GA 30059, (770) 948–3556; and Southern Cross Ranch, 1670 Bethany Church Road, Madison, GA 30650, (706) 342–8027, meet the requirements of § 94.14(c). The Atlanta Equine Complex is located at the Atlanta Hartsfield International Airport; Tumbleweed Farm is located in the immediate vicinity of the airport; and Southern Cross Ranch is located less than 60 miles from the airport. If these facilities become approved export inspection facilities, veterinarians of the Animal and Plant Health Inspection Service would conduct export inspections of animals at these facilities by appointment. Exporters using the Atlanta Equine Complex would have direct access to the airport, and exporters using Tumbleweed Farm would be able to transport their animals to the airport in approximately 15 minutes. Exporters using Southern Cross Ranch would be able to transport their animals to the airport in approximately 1 hour.

Therefore, we are proposing to amend § 91.14(a) to add Atlanta Hartsfield International Airport, Atlanta, GA, as a port of embarkation and add the Atlanta Equine Center, Atlanta, GA, Tumbleweed Farm, Mableton, GA, and Southern Cross Ranch, Madison, GA, to the list of export inspection facilities.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

This proposed rule would designate Atlanta Hartsfield International Airport as a port of embarkation and three facilities in Georgia—the Atlanta Equine Complex in Atlanta, Tumbleweed Farm in Mableton, and Southern Cross Ranch in Madison—as approved export inspection facilities. The Atlanta Equine Complex and Tumbleweed Farm are located in the immediate vicinity of the Atlanta Hartsfield International Airport. The location of Southern Cross Ranch is less than 60 miles from the airport, or approximately an hour's driving time, and would offer businesses within the Madison, GA, area a convenient alternative location at which animals destined for export could receive inspections.

We do not expect that designating these three facilities as export inspection facilities and Atlanta Hartsfield International Airport as a port of embarkation would have any adverse impact on businesses. These proposed actions should benefit exporters of animals in the region by reducing their animal transportation costs. Currently, the closest designated ports of embarkation from which exporters in Georgia may ship their animals are in Kentucky and Florida. From past export activity in the area, we anticipate that, at least initially, if these proposed actions are made final, a yearly average of about 50 exportations of animals, mostly horses and some goats, would take place through Atlanta.

Under these circumstances, the Administrator of the Animal and Plant

Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 91

Animal diseases, Animal welfare, Exports, Livestock, Reporting and recordkeeping requirements, Transportation.

Accordingly, 9 CFR part 91 would be amended as follows:

PART 91—INSPECTION AND HANDLING OF LIVESTOCK FOR EXPORTATION

1. The authority citation for part 91 would continue to read as follows:

Authority: 21 U.S.C. 105, 112, 113, 114a, 120, 121, 134b, 134f, 136, 136a, 612, 613, 614, 618; 46 U.S.C. 466a, 466b; 49 U.S.C. 1509(d); 7 CFR 2.22, 2.80, and 371.2(d).

2. In § 91.14, paragraphs (a)(3) through (a)(17) would be redesignated as paragraphs (a)(4) through (a)(18), and a new paragraph (a)(3) would be added to read as follows.

§ 91.14 Ports of embarkation and export inspection facilities.

(a) * * *

(3) *Georgia.*

(i) Atlanta Hartsfield International Airport.

(A) Atlanta Equine Complex, 1270 Woolman Place, Atlanta, GA 30354, (404) 767–1700.

(B) Tumbleweed Farm (horses only), 1677 Buckner Road, Mableton, GA 30059, (770) 948–3556.

(C) Southern Cross Ranch (horses only), 1670 Bethany Church Road, Madison, GA 30650, (706) 342–8027.

* * * * *

Done in Washington, DC, this 1st day of October 1996.

A. Strating,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–25638 Filed 10–04–96; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20, 32, 35, 36, 39

RIN 3150–AF46

Minor Corrections, Clarifying Changes, and a Minor Policy Change

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its regulations to make minor corrections and clarifying changes to the standards for protection against radiation. The proposed amendments would also conform other parts with the Commission's revised radiation protection requirements. In addition, a minor policy change is proposed that would revise the monitoring criterion for minors from 0.05 rem (0.5 mSv) to 0.1 rem (1 mSv) in a year and for declared pregnant women from 0.05 rem (0.5 mSv) to 0.1 rem (1 mSv) during their pregnancies. Revising the monitoring criterion would not, in any way, raise the dose limit for declared pregnant women and minors. Licensees would still be required to ensure that the dose limit of 0.5 rem (5 mSv) for minors is not exceeded in a year and that the dose limit of 0.5 rem (5 mSv) for declared pregnant women is not exceeded during the period of their pregnancy. The dose limit for the embryo/fetus is unchanged. This proposed rule is necessary to inform the public of these minor changes to the NRC's regulations and invite comments.

DATES: Comment period expires December 23, 1996. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; Attention: Docketing and Service Branch.

Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 am and 4:15 pm Federal workdays.

Copies of the supporting statement submitted to OMB and comments received may be examined at the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC.

For information on submitting comments electronically, see the discussion under Electronic Access in the Supplementary Information section.

FOR FURTHER INFORMATION CONTACT: Jayne M. McCausland, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415–6219, e-mail JMM2@nrc.gov.

SUPPLEMENTARY INFORMATION:

On May 21, 1991 (56 FR 23360), a final rule was published in the Federal Register that amended 10 CFR Part 20 to update the NRC's ''Standards for Protection Against Radiation.'' Subsequent amendments were published to (1) change the mandatory implementation date to January 1, 1994, and make conforming changes to the text to reflect the new implementation date (57 FR 38588; August 26, 1992), (2) remove or modify provisions to reflect the new implementation date for NRC's revised ''Standards for Protection Against Radiation'' (58 FR 67657; December 22, 1993), and (3) restore provisions inadvertently removed or modified (59 FR 41641; August 15, 1994; and 60 FR 20183; April 25, 1995). This proposed rule would make additional minor corrections and clarifying changes to the NRC regulation for greater clarity and to further facilitate implementation. The proposed rule would also make conforming amendments to 10 CFR Parts 32, 35, 36, and 39. In addition, a minor policy change is proposed that would revise the monitoring criterion for minors from 0.05 rem (0.5 mSv) to 0.1 rem (1 mSv) in a year and for declared pregnant women from 0.05 rem (0.5 mSv) to 0.1 rem (1 mSv) during their pregnancies.

This proposed rule would make the following changes:

(1) In § 20.1003, ''Definitions,'' clarifying changes and minor corrections would be made to the following:

(a) The term ''Airborne radioactivity area'' would be replaced with ''Airborne radioactive material area'' to clarify that radioactivity is a property of matter and, as such, cannot be airborne. A conforming change would also be made in § 20.1902(d) to permit licensees the option of either using the current signs or posting new signs to reflect this change.

(b) The definition of ''Declared pregnant woman'' would be revised to specify that the written declaration of pregnancy would be given to the licensee. This is necessary to ensure that the licensee responsible for work assignments involving exposure is aware of the declaration of pregnancy so that appropriate dose restriction can be imposed. The change would also specify the duration of the effectiveness of a woman's declaration.

(c) The term ''Eye dose equivalent'' (EDE) would be replaced with ''Lens dose equivalent'' (LDE) to avoid confusion between the initialisms for dose to the lens of the eye and effective dose equivalent (EDE).

(d) The definitions of ''High radiation area'' and ''Very high radiation area'' would be revised to make it clear that these area designations are based solely on radiation levels from sources external to an individual who may receive the dose.

(e) The definition of ''Individual monitoring devices'' would be revised to correct the terminology for thermoluminescence dosimeters.

(2) In § 20.1101(b), the word ''practicable'' would be changed to ''practical'' to remove the basis for an incorrect perception among some licensees that, by using the word ''practicable'' in this section, the NRC is requiring licensees to use any dose averting technique that is capable of being used even if the technique is unproven or impractical.

(3) In §§ 20.1201 (a)(2)(i) and (c); 20.1203; 20.2101; 20.2106(a)(1); and 20.2202 (a)(1)(ii) and (b)(1)(ii), ''eye dose equivalent'' would be replaced by ''lens dose equivalent'' to conform to the proposed amendment in § 20.1003.

(4) In § 20.1206, Planned special exposures, paragraph (a) would be revised to clarify the meaning of ''higher exposure.'' The proposed new wording would state that planned special exposures are authorized only in exceptional situations when alternatives that might avoid the dose are unavailable or impractical.

(5) In § 20.1208 (a), (c), (c)(2), and (d), the phrase ''dose to an embryo/fetus'' would be changed to read ''dose equivalent to the embryo/fetus'' to make it clear that the dose limit specifically applies to the dose equivalent, which is the technically correct term to denote effect of dose to an organ.

(6) In § 20.1501(a)(2)(i), the phrase ''The extent of radiation levels;* * *'' would be revised to read ''The magnitude and extent of radiation levels;* * *.'' to more clearly reflect the intended meaning.

(7) In § 20.1501(a)(2)(iii), the phrase ''The potential radiological hazards that could be present'' would be revised to read ''The potential radiological hazards'' to remove the redundancy.

(8) In § 20.1502, the words ''from radiation sources under the control of the licensee'' would be added after ''exposure to radiation'' in paragraph (a) to improve clarity and to make it clear that a licensee is not responsible for sources not under its control.

(9) In § 20.1502 (a)(2) and (b)(2), monitoring requirements are stated as one-tenth of applicable limits for a year for minors and pregnant women, even though the dose limits referenced in paragraph (a)(2) apply for an entire year to minors while the dose limit referenced in paragraph (b)(2) applies only to the 9-month gestation period of a declared pregnant woman. These paragraphs would be separated and revised accordingly to make this section consistent with § 20.1208 and technically correct. In addition, the criterion for monitoring minors and declared pregnant women would be changed for minors from 0.05 rem (0.5 mSv) to 0.1 rem (1 mSv) in a year and for declared pregnant women from 0.05 rem (0.5 mSv) to 0.1 rem (1 mSv) during their pregnancies. This change would constitute a small licensee burden reduction with no loss in worker health and safety. The conservative approach currently in use has resulted in the following problems:

(a) The value is not consistent with the 0.1 rem (1 mSv) dose limit for members of the public in § 20.1301(a). It is not appropriate to require monitoring of workers who are expected to receive less dose than is permitted for members of the public; and

(b) The value is not consistent with the 100-mrem (1 mSv) training criterion in the recently revised § 19.12 (60 FR 36038; July 13, 1995).

Raising this limit would not, in any way, raise the dose limit for declared pregnant women and minors. Licensees would still be required to ensure that the dose limit of 0.5 rem (5 mSv) for minors is not exceeded in a year and that the dose limit of 0.5 rem (5 mSv) for declared pregnant women is not exceeded during the period of their pregnancy.

(10) In § 20.1902(d), a proposed change to the posting requirement would permit the use of the words ''Airborne Radioactive Material Area'' in place of the currently required ''Airborne Radioactivity Area.'' The proposed change would also permit the continued use of existing stocks of signs with the currently required ''Airborne Radioactivity Area.'' This would conform to the proposed amendment in § 20.1003.

(11) In § 20.1903, a new paragraph would be added to exempt teletherapy rooms in a hospital from posting requirements as long as access is controlled to prevent the exposure of workers, other patients, and members of the public to radiation. The purpose of this change is to bring the regulation into conformity with existing licensing practices which avoid the unwarranted and potentially unsettling effect that ''GRAVE DANGER, VERY HIGH RADIATION AREA'' signs may have on patients.

(12) In § 20.1906(d), a revision would require licensees to notify the NRC Operations Center, instead of an NRC Regional Office, upon receiving and opening packages when radiation levels exceed regulatory limits. This would provide for consistency within the prompt notification requirements contained in § 20.2201. A conforming change also would be made to the prompt notification requirements in § 20.2202.

(13) In § 20.2101, a revision would permit licensees to include both the new SI units and the old (special) units of dose on records required by this part. Each of the recorded dose quantities would be recorded in the appropriate special unit and, if so desired, followed by the appropriate SI unit in parentheses. The term ''eye dose equivalent'' would be replaced by ''lens dose equivalent'' to conform to the proposed amendment in § 20.1003.

(14) In § 20.2106 (a)(2) and (a)(3), the references to ''body burden'' would be removed because this term is obsolete and is not defined in revised 10 CFR Part 20. Section 20.2106(a)(4) would be revised by adding a reference to § 20.1204(a), which requires licensees to take measurements of (1) concentrations of radioactive materials in air in work areas, or (2) quantities of radionuclides in the body, or (3) quantities of radionuclides excreted from the body, or (4) combinations of these measurements in order to determine internal dose when required by § 20.1502 to monitor internal dose. This, in effect, uses recorded concentrations of radioactive material in air, quantities of radioactive material determined to be in the body, or excreta, or any combination of these that would be needed, instead of ''body burden,'' for assessing the committed effective dose equivalent (CEDE). The NRC believes that this information is clearly necessary to support the recorded results of the licensee's calculation of CEDE. Adding this reference would not impose any additional recordkeeping burden on

licensees because they are required to obtain this information in order to calculate CEDE under § 20.1204.

(15) A revision to § 20.2202(d) would result in the application of the same incident reporting requirements to all licensees. Currently, this section requires that power reactor licensees submit reports to the NRC Operations Center, but all other licensees must submit both a telephone report to the NRC Operations Center and a telegram, mailgram, or facsimile to the Regional Office. This change would require all licensees to report incidents by telephone to the NRC Operations Center ensuring consistency in the prompt notification requirements contained elsewhere in this part and would result in a reduction in the information collection burden.

(16) In § 32.54(a), the reference to ''§ 20.203(a)'' would be corrected to read ''§ 20.1901.''

(17) In § 35.20, ''ALARA program,'' paragraph (c) would be removed as redundant because the requirements that are to be addressed in the ALARA program are contained in 10 CFR Part 20, and the training requirements are addressed in 10 CFR 19.12. Part 35 references both Parts 19 and 20 as containing requirements for medical licensees.

(18) Safety precautions and survey requirements for restricted and unrestricted areas are specified in §§ 35.315, 35.415, 35.641, and 35.643. Sections 35.315(a)(4) and 35.415(a)(4) would be revised to remove the words ''restricted'' and ''unrestricted'' where they modify the word ''area.'' Sections 35.641(a)(2)(i) and (a)(2)(ii) and 35.643(a) would be revised to be consistent with definitions of dose to occupationally exposed individuals and dose to members of the public. Also, in § 35.643(a)(1), a misreference to § 20.1301(c) would be corrected to read § 20.1301. The 0.5 rem (5 mSv) limit permitted by application and NRC approval under § 20.1301(c) was never intended to be required under this section in Part 35. Rather, it was always the intent of the NRC to apply the 0.1 rem (1 mSv) limit in § 20.1301(a) to this section, with the provision for licensees to request the 0.5 rem limit specified in § 20.1301(c).

(19) In § 36.23(g), posting requirements for a panoramic irradiator would be revised to conform with posting requirements for high or very high radiation areas in § 20.1902. The posting requirements in Part 36 currently require a posting appropriate to a high radiation area only.

(20) In § 39.33, ''Radiation detection instruments,'' a conforming change to paragraph (a) would be made by replacing the term ''milliroentgens'' with the term ''millirems'' to be consistent with revised Part 20 terminology. Because the NRC recognizes that most licensees may still use radiation detection instruments that measure radiation in units of roentgens, measurements taken in roentgens could continue to be recorded in terms of the roentgen, provided that the measurements can be readily converted to rem for records required under 10 CFR Part 20.2101(a).

(21) In § 39.71(b), the reference to ''§ 20.3'' would be corrected to read ''§ 20.1003.''

Electronic Access

Comments on the proposed rule may also be submitted electronically in either ASCII text or Wordperfect format (version 5.1 or later) by calling the NRC Electronic Bulletin Board on FedWorld. The bulletin board may be accessed using a personal computer, a modem, and one of the commonly available communications software packages, or directly via Internet.

If using a personal computer and modem, the NRC rulemaking subsystem on FedWorld can be accessed directly by dialing the toll free number: 1–800–303–9672. Communication software parameters should be set as follows: parity to none, data bits to 8, and stop bits to 1 (N,8,1). Use ANSI or VT–100 terminal emulation. The NRC rulemaking systems can then be accessed by selecting the ''Rules Menu'' option from the ''NRC Main Menu.'' For further information about options available for NRC at FedWorld, consult the ''Help/Information Center'' from the ''NRC Main Menu.'' Users will find the ''FedWorld Online User's Guides'' particularly helpful. Many NRC subsystems and databases also have a ''Help/Information Center'' option that is tailored to the particular subsystem.

The NRC subsystem on FedWorld can also be accessed by a direct dial phone number for the main FedWorld BBS: 703–321–3339; Telnet via Internet: fedworld.gov (192.239.92.3); File Transfer Protocol (FTP) via Internet: ftp.fedworld.gov (192.239.92.205); and World Wide Web using the ''Home Page'': www.fedworld.gov (this is the Uniform Resource Locator (URL)). If you contact FedWorld using Telnet, you will see the NRC area and menus, including the Rules Menu. Although you will be able to download documents and leave messages, you will not be able to write comments or upload files (comments). If you contact FedWorld using FTP, all files can be accessed and downloaded but uploads are not allowed; all you will see is a list of files without descriptions (normal Gopher look). An index file listing all files within a subdirectory, with descriptions, is available. There is a 15-minute time limit for FTP access.

Although FedWorld also can be accessed through the World Wide Web, like FTP that mode only provides access for downloading files and does not display the NRC Rules Menu.

If using a method other than the NRC's toll free number to contact FedWorld, the NRC subsystem will be accessed from the main FedWorld menu by selecting ''F—Regulatory, Government Administration and State Systems'' or by entering the command ''/go nrc'' at a FedWorld command line. At the next menu, select ''A—Regulatory Information Mall,'' and then select ''A—U.S. Nuclear Regulatory Commission'' at the next menu. If you access NRC from FedWorld's ''Regulatory, Government Administration'' menu, you may return to FedWorld by selecting the ''Return to FedWorld'' option from the ''NRC Main Menu.'' However, if you access NRC at FedWorld by using NRC's toll-free number, you will have full access to all NRC systems, but you will not have access to the main FedWorld system. For more information on NRC bulletin boards, call Mr. Arthur Davis, Systems Integration and Development Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–5780; e-mail AXD3@nrc.gov.

Agreement State Compatibility

This rulemaking will be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency of State and Federal safety requirements. The NRC has determined that a Division 2 level of compatibility should be assigned to the changes to §§ 20.1003, 20.1101, 20.1201, 20.1206, 20.1208, 20.1501, 20.1502, 20.1902, 20.1903, 20.1906, 20.2101, 20.2106, 20.2202, 32.54, 35.20, 35.315, 35.415, 35.641, 35.643, 36.23, 39.33, and 39.71 because the requirements in these sections already have been assigned a Division 2 level of compatibility. This rulemaking is primarily of a clarifying nature so the basis for that assignment should not change.

Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed rule is the type of action described in the categorical exclusion in 10 CFR 51.22(c)(2). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed rule.

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

The rule will reduce existing information collection requirements, and the public burden for this collection of information is expected to be reduced by approximately 250 hours per year over the entire industry. This reduction includes the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the collection of information contained in the proposed rule and on the following issues:

1. Is the proposed collection of information necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the estimate of burden accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the collection of information be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed collection of information, including suggestions for reducing the burden, to the Information and Records Management Branch (T–6F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–10202, (3150–0014), Office of Management and Budget, Washington, DC 20503.

Comments to OMB on the collection of information or on the above issues should be submitted by (November 6, 1996. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

The NRC 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.

Regulatory Analysis

This proposed rule makes minor correcting and clarifying amendments to the requirements in 10 CFR Part 20 and conforms 10 CFR Parts 32, 35, 36, and 39 to 10 CFR Part 20. The proposed rulemaking would not impose any additional costs on licensees since the rulemaking would be correcting and clarifying several definitions and current requirements addressing standards for protection against radiation. No impact is anticipated to result from any of the proposed correcting or clarifying amendments. Because the proposed rule would improve clarity and consistency in the NRC's regulations, it would benefit the licensees.

The proposed amendments should result in a minor reduction in burden to licensees by eliminating written reports and allowing licensees to submit incident reports by telephone. This proposed change is consistent with the Paperwork Reduction Act. The proposed requirements also would waive posting requirements in teletherapy rooms in hospitals because of the unsettling effects that the signs have on patients. There would be no decrease in safety because the safety precautions in 10 CFR Part 35 are considered adequate to protect individuals from inadvertent exposure to radiation. This proposed change would have a beneficial effect on patients.

In addition, these proposed amendments would change the monitoring requirement for minors and pregnant women from one-tenth of the applicable limit or 0.05 rem (0.5 mSv) to 0.1 rem (1 mSv) for the following reasons:

(1) The value is consistent with the 100 mrem (1 mSv) training criterion in the recently revised 10 CFR 19.12 (60 FR 36038; July 13, 1995). Thus, monitoring would not be required at any dose below that requiring the training of workers.

(2) The value is consistent with the 0.1 rem (1 mSv) dose limit for members of the public in 10 CFR 20.1301(a). It is not necessary or appropriate to require monitoring of workers who are expected to receive less dose than is permitted for members of the public. There may be some reduction in burden, but any reduction would be small, and because of the many factors that impact the decision as to whether personal dosimeters will be worn, it is impossible to assess this likely small burden reduction.

This discussion constitutes the regulatory analysis for this proposed rule.

Backfit Analysis

The NRC has determined that the backfit rule in § 50.109 does not apply to this proposed rule and, therefore, that a backfit analysis is not required for this proposed rule because these amendments do not involve any provision that would impose backfits as defined in § 50.109(a)(1).

List of Subjects

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 36

Byproduct material, Criminal penalties, Nuclear material, Oil and gas exploration—well logging, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Source material, Special nuclear material.

10 CFR Part 39

Byproduct material, Criminal penalties, Nuclear material, Oil and gas exploration—well logging, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Source material, Special nuclear material.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 continues to read as follows:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232,

2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

2. In § 20.1003, the definitions of *Airborne radioactivity area* and *Eye dose equivalent* are removed. The definitions of *Airborne radioactive material area* and *Lens dose equivalent* are added in alphabetical order, and the definitions of *Declared pregnant woman, High radiation area, Individual monitoring devices,* and *Very high radiation area* are revised to read as follows:

§ 20.1003 Definitions.

* * * * *

Airborne radioactive material area means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations—

(1) In excess of the derived air concentrations (DACs) specified in Appendix B to §§ 20.1001–20.2402; or

(2) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours that an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

* * * * *

Declared pregnant woman means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

* * * * *

High radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

* * * * *

Individual monitoring devices (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal (''lapel'') air sampling devices.

* * * * *

Lens dose equivalent applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

* * * * *

Very high radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in 1 hour at 1 meter from a radiation source or 1 meter from any surface that the radiation penetrates.

* * * * *

3. In § 20.1101, paragraph (b) is revised to read as follows:

§ 20.1101 Radiation protection programs.

* * * * *

(b) The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

* * * * *

4. In § 20.1201, paragraphs (a)(2)(i) and (c) are revised to read as follows:

§ 20.1201 Occupational dose limits for adults

(a) * * *

(2) * * *

(i) A lens dose equivalent of 15 rems (0.15 Sv); and

* * * * *

(c) The assigned deep-dose equivalent and shallow-dose equivalent must be for the part of the body receiving the highest exposure. The deep-dose equivalent, lens dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

* * * * *

5. In § 20.1203, the introductory text is revised to read as follows:

§ 20.1203 Determination of external dose from airborne radioactive material.

Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep-dose equivalent, lens dose equivalent, and shallow-dose equivalent from external exposure to the radioactive cloud (see appendix B to part 20, footnotes 1 and 2).

* * * * *

6. In § 20.1206, paragraph (a) is revised to read as follows:

§ 20.1206 Planned special exposures.

* * * * *

(a) The licensee authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid any additional dose estimated to result from the planned special exposure are unavailable or impractical.

* * * * *

7. In § 20.1208, the section heading, paragraph (a), the introductory text of paragraph (c), and paragraphs (c)(2) and (d) are revised to read as follows:

§ 20.1208 Dose equivalent to an embryo/fetus.

(a) The licensee shall ensure that the dose equivalent to the embryo/fetus during the entire pregnancy as a result of the occupational exposure of a declared pregnant woman does not exceed 0.5 rem (5 mSv). (For recordkeeping requirements, see § 20.2106.)

* * * * *

(c) The dose equivalent to the embryo/fetus is the sum of—

* * * * *

(2) The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

(d) If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee, the licensee shall be deemed to be in compliance with paragraph (a) of this section if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

8. In § 20.1501, paragraphs (a)(2)(i) and (a)(2)(iii) are revised to read as follows:

§ 20.1501 General.

(a) * * *

(2) * * *

(i) The magnitude and extent of radiation levels;

* * * * *

(iii) The potential radiological hazards.

* * * * *

9. In § 20.1502, paragraph (a)(3) is redesignated as (a)(4) and revised and new paragraphs (a)(3) and (b)(3) are added; and the introductory text of paragraph (a) and paragraphs (a)(2), (b)(1), and (b)(2) are revised to read as follows:

§ 20.1502 Conditions requiring individual monitoring of external and internal occupational dose.

* * * * *

(a) Each licensee shall monitor occupational exposure to radiation from radiation sources under the control of the licensee and shall supply and

require the use of individual monitoring devices by—

* * * * *

(2) Minors likely to receive, in 1 year, from radiation sources external to the body, a dose equivalent in excess of 0.1 rem (1 mSv);

(3) Declared pregnant women likely to receive, during the entire pregnancy from radiation sources external to the body, a dose equivalent in excess of 0.1 rem (1 mSv); and

(4) Individuals entering a high or very high radiation area.

(b) * * *

(1) Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) in table 1, Columns 1 and 2, of Appendix B to §§ 20.1001–20.2402;

(2) Minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.1 rem (1 mSv); and

(3) Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

10. In § 20.1902, paragraph (d) is revised to read as follows:

§ 20.1902 Posting requirements.

* * * * *

(d) *Posting of airborne radioactive material areas.* The licensee shall post each airborne radioactive material area with a conspicuous sign or signs bearing the radiation symbol and the words ''CAUTION, AIRBORNE RADIOACTIVITY AREA''; ''DANGER, AIRBORNE RADIOACTIVITY AREA''; ''CAUTION, AIRBORNE RADIOACTIVE MATERIAL AREA''; or ''DANGER, AIRBORNE RADIOACTIVE MATERIAL AREA.''

* * * * *

11. In § 20.1903, a new paragraph (d) is added to read as follows:

§ 20.1903 Exceptions to posting requirements.

* * * * *

(d) Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under § 20.1902 if—

(1) Access to the room is controlled pursuant to § 35.615; and

(2) Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this part.

12. In § 20.1906, the introductory text of paragraph (d) is revised to read as follows:

§ 20.1906 Procedures for receiving and opening packages.

* * * * *

(d) The licensee shall immediately notify the final delivery carrier and the NRC Operations Center (301–816–5100), by telephone, when—

* * * * *

13. In § 20.2101, paragraph (c) is redesignated as paragraph (d) and revised, paragraph (b) is redesignated as paragraph (c) and revised, and a new paragraph (b) is added to read as follows:

§ 20.2101 General provisions.

* * * * *

(b) In the records required by this part, the licensee may record quantities in SI units in parentheses following each of the units specified in paragraph (a) of this section. However, all quantities must be recorded as stated in paragraph (a) of this section.

(c) Notwithstanding the requirements of paragraph (a) of this section, when recording information on shipment manifests, as required in § 20.2006(b), information must be recorded in the International System of Units (SI) or in SI and units as specified in paragraph (a) of this section.

(d) The licensee shall make a clear distinction among the quantities entered on the records required by this part (e.g., total effective dose equivalent, shallow-dose equivalent, lens dose equivalent, deep-dose equivalent, committed effective dose equivalent).

14. In § 20.2106, paragraphs (a)(1), (a)(2), (a)(3), and (a)(4) are revised to read as follows:

§ 20.2106 Records of individual monitoring results.

(a) * * *

(1) The deep-dose equivalent to the whole body, lens dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities;

(2) The estimated intake of radionuclides (see § 20.1202);

(3) The committed effective dose equivalent assigned to the intake of radionuclides;

(4) The specific information used to assess the committed effective dose equivalent pursuant to § 20.1204 (a) and (c), and when required by § 20.1502; and

* * * * *

15. In § 20.2202, paragraphs (a)(1)(ii), (b)(1)(ii), and (d)(2) are revised to read as follows:

§ 20.2202 Notification of incidents.

(a) * * *

(1) * * *

(ii) A lens dose equivalent of 75 rems (0.75 Sv) or more; or

(b) * * *

(1) * * *

(ii) A lens dose equivalent exceeding 15 rems (0.15 Sv); or

(d) * * *

(2) All other licensees shall make the reports required by paragraphs (a) and (b) of this section by telephone to the NRC Operations Center (301) 816–5100.

* * * * *

PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

16. The authority citation for part 32 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

§ 32.54 [Amended]

17. In § 32.54, paragraph (a) is amended by removing the reference ''§ 20.203(a)'' and adding ''§ 20.1901.''

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

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

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

§ 35.20 [Amended]

19. In § 35.20, paragraph (c) is removed.

20. In § 35.315, paragraph (a)(4) is revised to read as follows:

§ 35.315 Safety precautions.

(a) * * *

(4) Promptly after administration of the dosage, measure the dose rates in contiguous areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of part 20 of this chapter, and retain for 3 years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at each point surveyed expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

* * * * *

21. In § 35.415, paragraph (a)(4) is revised to read as follows:

§ 35.415 Safety precautions.

(a) * * *

(4) Promptly after implanting the material, survey the dose rates in contiguous areas with a radiation measurement survey instrument to demonstrate compliance with the

requirements of part 20 of this chapter, and retain for 3 years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several of these points expressed in millirem per hour, the instrument used to make the survey, and the name of the individual who made the survey.

* * * * *

22. In § 35.641, paragraphs (a)(2)(i) and (a)(2)(ii) are revised to read as follows:

§ 35.641 Radiation surveys for teletherapy facilities.

(a) * * *

(2) * * *

(i) Radiation dose rates in restricted areas are not likely to cause any occupationally exposed individual to receive a dose in excess of the limits specified in § 20.1201 of this chapter; and

(ii) Radiation dose rates in unrestricted areas are not likely to cause any individual member of the public to receive a dose in excess of the limits specified in § 20.1301 of this chapter.

* * * * *

23. In § 35.643, paragraphs (a) introductory text and (a)(1) are revised to read as follows:

§ 35.643 Modification of teletherapy unit or room before beginning a treatment program.

(a) If the survey required by § 35.641 indicates that any individual member of the public is likely to receive a dose in excess of the limits specified in § 20.1301 of this chapter, the licensee shall, before beginning the treatment program:

(1) Either equip the unit with stops or add additional radiation shielding to ensure compliance with § 20.1301 of this chapter.

* * * * *

PART 36—LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

24. The authority citation for part 36 continues to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

25. In § 36.23, paragraph (g) is revised to read as follows:

§ 36.23 Access control.

* * * * *

(g) Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must be posted as required by § 20.1902. Radiation postings for panoramic irradiators must comply with the posting requirements of § 20.1902, except that signs may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

* * * * *

PART 39—LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

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

Authority: Secs. 53, 57, 62, 63, 65, 69, 81, 82, 161, 182, 183, 188, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

27. In § 39.33, paragraph (a) is revised to read as follows:

§ 39.33 Radiation detection instruments.

(a) The licensee shall keep a calibrated and operable radiation survey instrument capable of detecting beta and gamma radiation at each field station and temporary jobsite to make the radiation surveys required by this part and by part 20 of this chapter. To satisfy this requirement, the radiation survey instrument must be capable of measuring 0.1 mrem (0.001 mSv) per hour through at least 50 mrem (0.5 mSv) per hour.

* * * * *

§ 39.71 [Amended]

28. In § 39.71, paragraph (b) is amended by removing the reference to ''§ 20.3'' and adding ''§ 20.1003.''

Dated at Rockville, Maryland, this 5th day of September 1996.

For the Nuclear Regulatory Commission.

James M. Taylor,

Executive Director for Operations.

[FR Doc. 96–25486 Filed 10–4–96; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–NM–163–AD]

RIN 2120–AA64

Airworthiness Directives; Transport Category Airplanes Equipped with Day-Ray Products, Inc., Fluorescent Light Ballasts

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to any transport category airplane that is equipped with certain Day-Ray fluorescent light ballasts installed in the upper and/or lower cabin sidewall. This proposal would require a visual inspection to determine the type of fluorescent light ballasts installed in the cabin sidewall, and either the replacement of suspect ballasts or the installation of a protective cover over the ballast. This proposal is prompted by reports of smoke, fumes, and/or electrical fire emitting from the baggage bin of the aft passenger compartment due to the failure of the fluorescent light ballasts. The actions specified by the proposed AD are intended to prevent the potential for a fire in the passenger compartment resulting from failure of the fluorescent light ballast of the cabin sidewall.

DATES: Comments must be received by November 18, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–163–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Day Ray Products, Inc., 1133 Mission Street, South Pasadena, California 91031; or Hexcel Corporation, Heath Tecna Interiors, 3225 Woburn Street, Bellingham, Washington 98226; or McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Department C1–L51 (2–60).

This information may be examined at the FAA, Transport Airplane

Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, 3960 Paramount Boulevard, Lakewood, California.

FOR FURTHER INFORMATION CONTACT: J. Kirk Baker, Aerospace Engineer, Systems and Equipment Branch, ANM–130L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712; telephone (310) 627–5345; fax (310) 627–5210.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 96–NM–163–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–163–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

On May 22, 1996, the FAA issued AD 96–11–13, amendment 39–9638 (61 FR 27251, May 31, 1996) which is applicable to McDonnell Douglas Model DC–9–80 series airplanes and Model MD–88 airplanes. Among other things, that AD requires a visual inspection to determine the type of fluorescent light ballasts installed in the cabin sidewall; and either installation of a protective cover, replacement, or removal/disconnection, if necessary. That AD was prompted by at least two reports of smoke, fumes, and/or electrical fire emitting from the baggage bin of the aft passenger compartment and from the dust barriers of the outboard ceiling panel on McDonnell Douglas Model DC–9–82 (MD–82) series airplanes. Investigation revealed that the design of certain Day-Ray Products fluorescent light ballast assemblies, as installed on the incident airplanes, allows moisture condensation to enter into the ballast case during altitude changes. The effects of such moisture subsequently contaminate the printed circuit card, which can result in a short circuit that ruptures the ballast casing and emits fire. This condition, if not corrected, could result in a fire in the passenger compartment.

Since issuance of that AD, the FAA has identified additional light ballasts manufactured by Day-Ray that are susceptible to the same problems addressed by that AD. These suspect light ballasts may be installed in any number of models of transport category airplanes, and, specifically, on airplanes with interiors that have been configured by means of certain supplemental type certificates (STC) issued to C&D Aerospace and Heath Tecna Interiors. In order prevent the potential for a fire in the passenger compartment resulting from failure of the fluorescent light ballast of the cabin sidewall, the FAA has determined that additional AD action must be taken to address these light ballasts.

Explanation of Relevant Service Information

The FAA has reviewed and approved the following service bulletins, each of which describes procedures for inspecting light ballasts to determine their part number, removing suspect ballasts, and installing improved ballasts that are manufactured by Bruce Industries:

1. McDonnell Douglas DC–9 Service Bulletin DC9–33–103, dated May 30, 1995;
2. McDonnell Douglas MD–80 Service Bulletin MD80–33A107, Revision 01, dated August 30, 1996;
3. McDonnell Douglas DC–10 Service Bulletin DC10–33–073, dated June 18, 1996;
4. Heath Tecna Alert Service Bulletin ESCI–33–A2, Revision 1, dated July 24, 1996, for all McDonnell Douglas Model DC–(MD–80) series airplanes retrofitted with the Heath Tecna Contemporary Deep Rack Interior (CDRI) and the Heath Tecna Extended Spacial Concept Interior (ESCI or ESCI III);
5. Heath Tecna Alert Service Bulletin MarkI–33–A2, Revision 1, dated July 24, 1996, for all McDonnell Douglas Model DC–8 series airplanes retrofitted with the Heath Tecna Mark I interior;
6. Heath Tecna Alert Service Bulletin MarkI–33–A3, Revision 1, dated July 24, 1996, for all Boeing Model 707 series airplanes retrofitted with the Heath Tecna Mark I interior;
7. Heath Tecna Alert Service Bulletin MarkI–33–A4, Revision 1, dated July 24, 1996, for all Boeing Model 727 series airplanes retrofitted with the heath Tecna Mark I interior;
8. Heath Tecna Alert Service Bulletin MarkI–33–A5, Revision 1, dated July 24, 1996, for all Boeing Model 737 series airplanes retrofitted with the Heath Tecna Mark I interior;
9. Heath Tecna Service Bulletin Spmk–33–A1, Revision 1, dated July 24, 1996, for all Boeing Model 727 series airplanes retrofitted with the Heath Tecna Spacemaker II or Spacemaker IIa interior;
10. Heath Tecna Service Bulletin Spmk–33–A2, Revision 1, dated July 24, 1996, for all Boeing Model 737 series airplanes retrofitted with the Heath Tecna Spacemaker II or Spacemaker IIa interior.

The FAA also has reviewed and approved Day-Ray Alert Service Bulletin 33A01, dated March 25, 1996, which describes procedures for installing a protective cover over the overhead and sidewall cabin lighting ballasts. This installation will minimize the possibility of uncontained smoke and flame due to failure of the ballasts.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require a one-time visual inspection to determine the type of fluorescent light ballasts installed in the upper and lower cabin sidewall. For airplanes on which any Day-Ray Products light ballast is installed, this AD also requires accomplishment of one of the following actions:

1. replacement of that ballast with a Bruce Industries light ballast, or
2. installation of a protective cover on the light ballast.

The actions would be required to be accomplished in accordance with the service bulletins described previously.

The proposed compliance time of 12 months for these actions was selected in

consideration of not only the safety implications associated with addressing the subject unsafe condition, but the availability of required parts and the practical aspect of accomplishing the required actions within an interval of time that parallels normally scheduled maintenance for the majority of affected operators.

Cost Impact

There are approximately 2,500 transport category airplanes of the affected design in the worldwide fleet. The FAA estimates that 1,800 airplanes of U.S. registry would be affected by this proposed AD.

To accomplish the proposed inspection, it would take approximately 6 work hours per airplane, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of this proposed inspection on U.S. operators is estimated to be $360 per airplane.

To replace the light ballasts would require approximately 33 work hours per airplane, at an average labor rate of $60 per work hour. Required parts would average approximately $8,550 per airplane, which represents a cost of $150 per ballast and an average of 57 ballasts per airplane. Based on these figures, the cost impact of this proposed replacement on U.S. operators is estimated to be $10,530 per airplane.

To modify the sidewall lighting by installing a protective cover would require approximately 18 work hours per airplane, at an average labor rate of $60 per work hour. Required parts would average approximately $285 per airplane, which represents a cost of $5 per cover and an average of 57 ballasts per airplane. Based on these figures, the cost impact of this proposed modification on U.S. operators is estimated to be $1,365 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would 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 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) 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 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, Safety.

The Proposed Amendment

Accordingly, pursuant to 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. Section 39.13 is amended by adding the following new airworthiness directive:

Transport Category Airplanes: Docket 96–NM–163–AD.

Applicability: Airplanes equipped with Day-Ray Products, Inc., cabin sidewall 0fluorescent light ballasts having part numbers listed in Table 1 of this AD; including, but not limited to, McDonnell Douglas Model DC–9, DC–9–80, MD–88, DC–10, and C–9 (military) series airplanes, and Boeing Model 707, 727, and 737 series airplanes; certificated in any category.

TABLE 1.—FLUORESCENT LIGHT BALLASTS SUBJECT TO THIS AD

Name	Part No.
Day Ray	69–10
	69–10–1
	69–68
	69–68–1
	69–69
	69–69–1
	70–94
	70–94–1
	83–12
	83–12–1

Note 1: This AD does not apply to airplanes that are equipped with solid state electronic light ballast systems.

Note 2: This AD applies to all transport category airplanes equipped with the light ballasts identified in the preceding applicability provision, regardless of whether the airplane 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 (c) 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 the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent the potential for a fire in the passenger compartment resulting from failure of the fluorescent light ballast of the cabin sidewall, accomplish the following:

(a) Within 12 months after the effective date of this AD, perform a one-time visual inspection to determine the type of fluorescent light ballasts installed in the upper and lower cabin sidewall. If any ballast installed has a part number that is listed in Table 1 of this AD, prior to further flight, accomplish the actions specified in either paragraph (a)(1) or (a)(2) of this AD:

(1) Remove the Day-Ray light ballast and replace it with a light ballast manufactured by Bruce Industries, in accordance with the applicable service bulletin(s) listed in Table 2 of this AD. Or

(2) Install a protective cover over the light ballast, in accordance with Day-Ray Alert Service Bulletin 33A01, dated March 25, 1996.

TABLE 2.—SERVICE BULLETINS CONTAINING INSTRUCTIONS FOR ACCOMPLISHING THE REQUIREMENTS OF THIS AD

Service bulletin number and date	Affected airplanes
McDonnell Douglas, DC–9 Service Bulletin DC9–33–103, May 30, 1995	Model DC–9–30, -40, and -50 series airplanes listed in effectivity of service bulletin.
McDonnell Douglas, MD–80 Service Bulletin MD80–33A107, Revision R01, August 30, 1996.	Model DC–9–80 series and Model MD–88 airplanes listed in effectivity of service bulletin.
McDonnell Douglas, DC–10 Service Bulletin DC10–33–073 June 18, 1996.	Model DC–10–10, -15, -30, and -40 series and KC–10A airplanes listed in effectivity of service bulletin
Heath Tecna, Alert Service Bulletin ESCI–33–A2, Revision 1, July 24, 1996.	McDonnell Douglas Model DC–9–80 (MD–80) series airplanes retrofitted with Heath Tecna Contemporary Deep Rack Interior (CDRI) and Heath Tecna Extended Special Concept Interior (ESCI or ESCI III)
Heath Tecna, Alert Service Bulletin MarkI–33–A2, Revision 1, July 24, 1996.	McDonnell Douglas Model DC–8 series airplanes retrofitted with Heath Tecna Mark I interior
Heath Tecna, Alert Service Bulletin MarkI–33–A3, Revision 1, July 24, 1996.	Boeing Model 707 series airplanes retrofitted with the Heath Tecna Mark I interior.
Heath Tecna, Alert Service Bulletin MarkI–33–A4, Revision 1, July 24, 1996.	Boeing Model 727 series airplanes retrofitted with the Heath Tecna Mark I interior.
Heath Tecna, Alert Service Bulletin MarkI–33–A5, Revision 1, July 24, 1996.	Boeing Model 737 series airplanes retrofitted with the Heath Tecna Mark I interior.
Heath Tecna, Service Bulletin Spmk MarkI–33–A1, Revision 1, July 24, 1996.	Boeing Model 727 series airplanes retrofitted with the Heath Tecna Spacemaker II or Spacemaker IIa interior.
Heath Tecna, Service Bulletin Spmk–33–A2, Revision 1, July 24, 1996	Boeing Model 737 series airplanes retrofitted with the Heath Tecna Spacemaker II or Spacemaker IIa interior.

(b) As of the effective date of this AD, no person shall install in the upper or lower cabin sidewall of any airplane a Day-Ray fluorescent light ballast having a part number listed in Table 1 of this AD, unless a protective cover is installed on the ballast in accordance with Day-Ray Alert Service Bulletin 33A01, dated March 25, 1996.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on September 30, 1996.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–25575 Filed 10–04–96; 8:45 am]

BILLING CODE 4910–13–U

14 CFR Part 71

[Airspace Docket No. 96–ANM–026]

Proposed Amendment of Class E Airspace; Forsyth, MT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This proposed rule would amend the Forsyth, Montana, Class E airspace to accommodate a new Global Positioning System (GPS) Standard Instrumnent Approach Procedure (SIAP) to the Tillett Field Airport. The area would be depicted on aeronautical charts for pilot reference.

DATES: Comments must be received on or before November 29, 1996.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Operations Branch, ANM–530, Federal Aviation Administration, Docket No. 96–ANM–026, 1601 Lind Avenue S.W., Renton, Washington 98055–4056.

The official docket may be examined at the same address.

An informal docket may also be examined during normal hours at the address listed above.

FOR FURTHER INFORMATION CONTACT: James C. Frala, ANM–532.4, Federal Aviation Administration, Docket No. 96–ANM–026, 1601 Lind Avenue S.W., Renton, Washington 98055–4056; telephone number: (206) 227–2535.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interest parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory aeronautical, economic, environmental, and energy related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No 96–ANM–026.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination at the address listed above both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this NPRM by submitting a request to the Federal Aviation Administration, Operations Branch, ANM–530, 1601 Lind Avenue S.W., Renton, Washington 98055–0456. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future

NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend Class E airspace at Forsyth, Montana, to accommodate a new GPS SIAP to the Tillett Field Airport. The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in Paragraph 6005 of FAA Order 7400.9D dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It. therefore, (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) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designation and Reporting Points, dated September 4, 1996, and effective September, 1996, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM MT E5 Forsyth, MT [Revised]

Forsyth, Tillitt Field, MT
(Lat. 46°16′16″N, long. 106°37′26″W)
Forsyth NDB
(Lat. 46°16′10″N, long. 106°31′03″W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of the Tillitt Field, and within 3.5 miles north and 4.3 miles south of the 075° bearing from the Forsyth NDB extending from the NDB to 8.7 miles east of the NDB; that airspace extending upward from 1,200 feet above the surface bounded on the north by the south edge of V–120, on the south by the north edge of V–2, and on the west by long. 107°00′00″W; excluding that portion which overlies the Miles City, Frank Wiley Field, MT, Class E airspace area.

* * * * *

Issued in Seattle, Washington, on September 26, 1996.

Glenn A. Adams II,

Assistant Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 96–25609 Filed 10–4–96; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 71

[Airspace Docket No. 96–AEA–09]

Proposed Establishment of Class E Airspace, Montauk, NY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would establish Class E airspace at Montauk, NY. A Very High Frequency Omni-Directional Range (VOR) and Global Positioning System (GPS) standard instrument approach procedure (SIAP) has been developed for Runway (RWY) 6 at Montauk Airport, Montauk, NY. The intended effect of this proposal is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations to the airport. The area would be depicted on aeronautical charts for pilot reference.

DATES: Comments must be received on or before November 1, 1996.

ADDRESSES: Send comments on the proposed rule in triplicate to: Manager, Operations Branch, AEA–530, Docket No. 96–AEA–09, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy Int'l Airport, Jamaica, NY 11430. The official docket may be examined in the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430.

An informal docket may also be examined during normal business hours in the Operations Branch, AEA–530, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430.

FOR FURTHER INFORMATION CONTACT: Mr. Francis T. Jordan, Jr., Airspace Specialist, Operations Branch, AEA–530, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York, 11430, telephone (718) 553–4521.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made ''Comments to Airspace Docket No. 96–AEA–09''. The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposal rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with the FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRN's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430. Communications must identify the

notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class E airspace extending upward from 700 feet above the surface (AGL) at Montauk, NY. A VOR or GPS RWY 6 SIAP has been developed for Montauk Airport. Additional controlled airspace extending upward from 700 feet above the surface (AGL) is needed to accommodate this SIAP and for IFR operations at the airport. The area would be depicted on appropriate aeronautical charts. Class E airspace designations for airspace extending upward from 700 feet above the surface are published in Paragraph 6005 of FAA Order 7400.9D dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposal regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposal regulation(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) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that would only affect air traffic procedures and air navigation, it is certified that this proposal rule would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposed to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120, E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, dated September 4, 1996, and effective September 16, 1996, is proposed to be amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AEA NY E5 Montauk, NY [New]

Montauk Airport, NY
(Lat. 41° 04′35″N, long. 71° 55′ 15''W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Montauk Airport and within 4 miles each side of the Hampton VORTAC 075° radial extending from the 6.5-mile radius to 10 miles northeast of the VORTAC and excluding that portion within the Block Island, RI 700 foot Class E Airspace Area.

* * * * *

Issued in Jamaica, New York, on September 24, 1996.

John S. Walker,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 96–25604 Filed 10–4–96; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF EDUCATION

34 CFR Parts 607, 608, 609, 628, 636, 637, 645, 647, 649, 650, 655, 658, 660, 661, and 669

RIN 1840–AC38

Removal of Regulations

AGENCY: Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to amend the Code of Federal Regulations (CFR) to remove certain regulations effective September 30, 1997. The regulations proposed to be removed are 34 CFR parts 607 (Strengthening Institutions Program), 608 (Strengthening Historically Black Colleges and Universities Program), 609 (Strengthening Historically Black Graduate Institutions Program), 628 (Endowment Challenge Grant Program), 636 (Urban Community Service Program), 637 (Minority Science Improvement Program), 645 (Upward Bound Program), 647 (Ronald E. McNair Postbaccalaureate Achievement Program), 649 (Patricia Roberts Harris Fellowship Program), 650 (Jacob K. Javits Fellowship Program), 655 (International Education Programs—General Provisions), 658 (Undergraduate International Studies and Foreign Language Program), 660 (The International Research and Studies Program), 661 (Business and International Education Program), and 669 (Language Resource Centers Program). As a result of a review in accordance with the President's regulatory reinvention initiative, the Secretary has determined that these regulations will no longer be needed after September 30, 1997.

DATES: Comments must be received on or before December 6, 1996.

ADDRESSES: All comments concerning these proposed regulations should be addressed to Alan Schiff, Office of Postsecondary Education, U.S. Department of Education, Suite 600, Portals Bldg., 600 Independence Avenue, SW, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: Alan Schiff, Office of Postsecondary Education, U.S. Department of Education at the address above or telephone: (202) 708–9027. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: President Clinton's memorandum of March 4, 1995, titled ''Regulatory Reinvention Initiative,'' directed heads of departments and agencies to review all existing regulations to eliminate those that are outdated and modify others to increase flexibility and reduce burden.

These programs will be administered on the basis of the applicable statute, the Education Department General Administrative Regulations and, in the case of parts 658 and 660, the remaining regulations in those parts. The removal of these regulations does not alter the obligations of current recipients of federal funds. The regulations in effect when a grant or other agreement is made govern that grant or agreement, unless otherwise specifically provided.

Parts 637, 658, 660, 661, and 669 were previously included in a notice of proposed rulemaking (NPRM) published on July 16, 1996 (61 FR 37184) that proposed amendments to these parts and the Education Department General Administrative Regulations (EDGAR) governing discretionary grant programs. The July 16 amendments proposed to establish new general EDGAR selection criteria for use by discretionary grant programs and to remove regulatory provisions made unnecessary by the amendments. No public comments were received on the proposed amendments to parts 637, 658, 660, 661, and 669.

Upon further review, the Secretary has determined that parts 637, 661, and 669 and additional sections of parts 658 and 660 can be removed. Since these changes are more extensive than the changes previously proposed, they are included in this NPRM for public comment and will not be included in final regulations based on the July 16 NPRM.

The Department is continuing to review its other existing regulations thoroughly in consultation with its customers and partners. To the extent the Secretary can identify further opportunities for regulatory reinvention, the Secretary will propose appropriate amendments to revise or eliminate outdated provisions, reduce burden, and increase flexibility.

Regulatory Flexibility Act Certification

The Secretary certifies that these proposed regulations would not have a significant economic impact on a substantial number of small entities. The removal of the regulations listed in this document would not have a significant economic impact on any of the entities affected.

Paperwork Reduction Act of 1995

These regulations have been examined under the Paperwork Reduction Act of 1995 and have been found to contain no information collection requirements.

Intergovernmental Review

Some of the programs that would be affected by these regulations are 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, this document is intended to provide early notification of the Department's specific plans and actions for these programs.

Invitation To Comment

Interested persons are invited to submit comments and recommendations regarding these proposed regulations.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in room 5100, FB–10, 600 Independence Avenue, SW, Washington, DC, between the hours of 9:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

Assessment of Educational Impact

The Secretary particularly requests comments on whether the proposed regulatory changes in this document would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects

334 CFR Part 607

Colleges and universities, Grant programs—education.

34 CFR Part 608

Colleges and universities, Grant programs—education.

34 CFR Part 609

Colleges and universities, Grant programs—education.

34 CFR Part 628

Colleges and universities, Grant programs—education.

34 CFR Part 636

Colleges and universities, Grant programs—education.

34 CFR Part 637

Colleges and universities, Grant programs—education, Minority groups, Science and technology, Women.

34 CFR Part 645

Colleges and universities, Grant programs—education, Student aid.

34 CFR Part 647

Colleges and universities, Grant programs—education, Student aid.

34 CFR Part 649

Colleges and universities, Grant programs—education, Scholarships and fellowships, Student aid.

34 CFR Part 650

Colleges and universities, Grant programs—education, Scholarships and fellowships, Student aid.

34 CFR Part 655

Colleges and universities, Foreign relations, Grant programs—education.

34 CFR Part 658

Colleges and universities, Educational study program, Foreign relations, Grant programs—education, Teachers.

34 CFR Part 660

Colleges and universities, Educational research, Foreign relations, Grant programs—education.

34 CFR Part 661

Business and industry, Colleges and universities, Exports, Foreign relations, Foreign trade, Grant programs—education.

34 CFR Part 669

Colleges and universities, Educational research, Foreign relations, Grant programs—education, Teachers.

(Catalog of Federal Domestic Assistance numbers do not apply.)

Dated: September 30, 1996.

David A. Longanecker,

Assistant Secretary for Postsecondary Education.

For reasons stated in the preamble, under the authority at 20 U.S.C. 1221e–3, the Secretary proposes to amend Title 34 of the Code of Federal Regulations, chapter VI, as follows:

PARTS 607, 608, 609, 628, 636, 637, 645, 647, 649, 650, 655, 661, and 669—[REMOVED]

1. Parts 607, 608, 609, 628, 636, 637, 645, 647, 649, 650, 655, 661, and 669 are removed.

PART 658—UNDERGRADUATE INTERNATIONAL STUDIES AND FOREIGN LANGUAGE PROGRAM

2. The authority citation for part 658 continues to read as follows:

Authority: 20 U.S.C. 1124, unless otherwise noted.

§§ 658.1, 658.2, 658.3, 658.4, 658.10, 658.11, 658.12, 658.30, 658.31, 658.32, 658.33, 658.34, 658.35, 658.41 [Removed]

3. Part 658 is amended by removing §§ 658.1, 658.2, 658.3, 658.4, 658.10, 658.11, 658.12, 658.30, 658.31, 658.32, 658.33, 658.34, 658.35, and 658.41 and by removing and reserving subparts A, B, and D.

PART 660—THE INTERNATIONAL RESEARCH AND STUDIES PROGRAM

4. The authority citation for part 660 continues to read as follows:

Authority: 20 U.S.C. 1125, unless otherwise noted.

§§ 660.1, 660.3, 660.4, 660.30, 660.31, 660.32, 660.33 [Removed]

5. Part 660 is amended by removing §§ 660.1, 660.3, 660.4, 660.30, 660.31, 660.32, and 660.33.

[FR Doc. 96–25440 Filed 10–04–96; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 043–0017b; FRL–5617–5]

Approval and Promulgation of State Implementation Plans; California State Implementation Plan Revision; Kern County Air Pollution Control District; Santa Barbara County Air Pollution Control District; South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the California State Implementation Plan (SIP) which concern the control of volatile organic compound (VOC) emissions from organic solvent degreasing operations, petroleum storage tank degassing, and gasoline transfer and dispensing operations. The intended effect of proposing approval of these rules is to regulate emissions of VOCs in accordance with the requirements of the Clean Air Act, as amended in 1990. In the Rules section of this Federal Register, EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial action and anticipates no adverse comments. A detailed rationale for this approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this action should do so at this time.

DATES: Comments on this proposed rule must be received in writing by November 6, 1996.

ADDRESSES: Written comments on this action should be addressed to: Daniel A. Meer, Rulemaking Section (A–5–3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Copies of the rules and EPA's evaluation report of each rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rules are also available for inspection at the following locations:

Environmental Protection Agency, Air Docket (6102), 401 ''M'' Street, S.W., Washington, D.C. 20460

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812

Kern County Air Pollution Control District, 2700 ''M'' Street, Suite 290, Bakersfield, CA 93301

Santa Barbara County Air Pollution Control District, 26 Castilian Drive, B–23, Goleta, CA 93117

South Coast Air Quality Management District, 21865 E. Copley Drive, Diamond Bar, CA 91765–4182

FOR FURTHER INFORMATION CONTACT: Mae Wang, Rulemaking Section (A–5–3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901, Telephone: (415) 744–1200.

SUPPLEMENTARY INFORMATION: This document concerns Kern County Air Pollution Control District (KCAPCD) Rule 412.1, Transfer of Gasoline into Vehicle Fuel Tanks; KCAPCD Rule 410.3, Organic Solvent Degreasing Operations; KCAPCD Rule 102, Definitions; Santa Barbara County Air Pollution Control District (SBCAPCD) Rule 343, Petroleum Storage Tank Degassing; and South Coast Air Quality Management District (SCAQMD) Rule 461, Gasoline Transfer and Dispensing. The California Air Resources Board submitted these rules for incorporation into the SIP. The following table contains the adoption and submittal dates for each rule.

Rule No.	Adopted	Submitted
KCAPCD 412.1	11/9/92	1/11/93
KCAPCD 410.3	3/7/96	5/10/96
KCAPCD 102	3/7/96	5/10/96
SBCAPCD 343	12/14/93	3/29/94
SCAQMD 461	9/8/95	1/31/96

For further information, please see the information provided in the direct final action which is located in the Rules section of this Federal Register.

Authority: 42 U.S.C. 7401–7671q.

Date Signed: September 17, 1996.

Felicia Marcus,

Regional Administrator.

[FR Doc. 96–25468 Filed 10–4–96; 8:45 am]

BILLING CODE 6560–50–W

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

49 CFR Parts 383 and 391

[FHWA Docket No. MC–93–23]

RIN 2125–AD20

Commercial Driver Physical Qualifications as Part of the Commercial Driver's License Process

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of meeting of negotiated rulemaking advisory committee.

SUMMARY: The FHWA announces the meeting date of an advisory committee (the Committee) established under the Federal Advisory Committee Act and the Negotiated Rulemaking Act to consider the relevant issues and attempt to reach a consensus in developing regulations governing the proposed merger of the State-administered commercial driver's license (CDL) procedures of 49 CFR Part 383 and the driver physical qualifications requirements of 49 CFR Part 391. The Committee is composed of persons who represent the interests that would be substantially affected by the rule.

The FHWA believes that public participation is critical to the success of this proceeding. Participation at meetings is not limited to Committee members. Negotiation sessions are open to the public, so interested parties may observe the negotiations and communicate their views in the appropriate time and manner to Committee members.

For a listing of Committee members, see the notice published on July 23, 1996, 61 FR 38133. Please note that the United Motorcoach Association and the American Bus Association will serve as full members of the Committee. For additional background information on this negotiated rulemaking, see the notice published on April 29, 1996, at 61 FR 18713.

DATES: The third meeting of the advisory committee will begin at 10 a.m. on October 22–23, 1996.

ADDRESSES: The third meeting of the advisory committee will be held at the Department of Transportation, Nassif Building, Room 4200, 400 7th Street, SW., Washington, DC. Subsequent meetings will be held at locations to be announced.

FOR FURTHER INFORMATION CONTACT: Ms. Teresa Doggett, Office of Motor Carrier Research and Standards, (202) 366–4001, or Ms. Grace Reidy, Office of Chief Counsel, (202) 366–0834, Federal

Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m. e.t., Monday through Friday, except Federal holidays.

Authority: [5 U.S.C. §§ 561–570; 5 U.S.C. App. 2 §§ 1–15]

Issued on: October 1, 1996.

Jill L. Hochman,

Acting Associate Administrator for Motor Carriers

[FR Doc. 96–25594 Filed 10–4–96; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AC01

Endangered and Threatened Wildlife and Plants; Withdrawal of the Proposed Rule to List the Plants Dudleya blochmaniae ssp. brevifolia (Short-leaved Dudleya) as Endangered, and Corethrogyne filaginifolia var. linifolia (Del Mar Sand-aster) as Threatened

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; withdrawal.

SUMMARY: The U.S. Fish and Wildlife Service (Service) withdraws the proposed rule, published in the Federal Register on October 1, 1993 (58 FR 51302), to list *Dudleya blochmaniae* ssp. *brevifolia* (short-leaved dudleya) as an endangered species and *Corethrogyne filaginifolia* var. *linifolia* (Del Mar sand-aster) as a threatened species under the Endangered Species Act of 1973, as amended (Act). Additional information has become available to the Service since publication of the proposed rule indicating that *Corethrogyne filaginifolia* var. *linifolia* is no longer recognized as taxonomically distinct and therefore does not qualify for listing under the Act. The threats to *Dudleya blochmaniae* ssp. *brevifolia* have decreased since the proposed rule was published. *Dudleya b.* ssp. *brevifolia* is considered a ''covered species'' within the Multiple Species Conservation Program (MSCP) of southern San Diego County. A substantial measure of interim protection is provided by a Resource Protection Ordinance of the City of San Diego. Upon final approval of the MSCP, anticipated in late 1996, it will provide preservation, monitoring, and management within the City of San Diego that addresses the conservation of this taxon.

ADDRESSES: The complete file for this rule is available for public inspection, by appointment, during normal business hours at the Carlsbad Field Office, U.S. Fish and Wildlife Service, 2730 Loker Avenue West, Carlsbad, California 92008.

FOR FURTHER INFORMATION CONTACT: Fred Roberts, Biologist (see **ADDRESSES** section) (telephone: 619/431–9440).

SUPPLEMENTARY INFORMATION:

Background

On October 1, 1993, the Service published in the Federal Register (58 FR 51302) a proposal to list six taxa of plants from southern maritime chaparral in San Diego and southern Orange counties, California, as endangered or threatened. *Corethrogyne filaginifolia* var. *linifolia* Hall (Del Mar sand-aster) was included in this proposal. The Service has received additional information regarding the taxonomic status of *C. filaginifolia* var. *linifolia* indicating that this taxon is not distinct from the more widespread *Lessingia filaginifolia* var. *filaginifolia* (Lane 1992, 1993). The Service has considered this new information and determines that the taxon does not qualify for listing under the Act. In determining the taxonomic validity of species, the Service applies current taxonomic understanding (usually as represented in published revisions and monographs). The status and/or validity of such taxa may be reevaluated in the future on the basis of new information.

Dudleya blochmaniae ssp. *brevifolia* Moran was proposed as endangered in the October 1, 1993, rule. Since the publication of the proposed rule, the MSCP, a regional planning effort in southwestern San Diego County, has been developed, is presently in a public review process, and has been submitted to the Service by the City of San Diego as part of an application for a section 10(a)(1)(B) incidental take permit for 85 species, including *Dudleya blochmaniae* ssp. *brevifolia.* The incidental take permit would be immediately effective only for listed species. The Service and the City of San Diego have jointly prepared a *Recirculated Environmental Impact Report/Environmental Impact Statement, Issuance of Take Authorizations for Threatened and Endangered Species due to Urban Growth within the Multiple Species Conservation Program (MSCP) Planning Area.* This document, released on August 30, 1996, for a 45-day public review period, assesses the effects of land-use decisions that will be made by local jurisdictions to implement the plan and the effects of the proposed issuance of the incidental take permit on the 85 species. A decision on the permit issuance is expected in late 1996.

The MSCP will, upon approval, set aside preservation areas and provide monitoring and management for the 85 ''covered species'' addressed in the City of San Diego permit application, including *Dudleya blochmaniae* ssp. *brevifolia.* ''Covered species'' are taxa that will be adequately conserved by the plan's proposed preservation and management. Of the six extant populations of *D. b.* ssp. *brevifolia,* four, including all the major populations, are within the City of San Diego and would be protected within the proposed MSCP preserve. Moreover, protection is currently afforded *D. b.* ssp. *brevifolia* populations located on State lands managed for habitat conservation (e.g., Torrey Pines State Park).

While some of these populations would still be subject to edge effects and recreational impacts related to the proximity of existing development (Crest Canyon, Torrey Pines State Park Extension) and proposed development (Carmel Mountain), proposed management in the MSCP would reduce existing threats to allow stabilization of *Dudleya b.* ssp. *brevifolia* (City of San Diego 1995; OGDEN 1995; U.S. Fish and Wildlife Service 1996; Cindy Burrescano, California Native Plant Society, *in litt.*, 1996). The Carmel Mountain population in the City of San Diego is the largest and most significant population of this taxon. The proposed preserve design, as defined by the MSCP, will provide for about 90 percent preservation at this site.

Although the MSCP has not yet been formally approved by the City of San Diego and most other participating jurisdictions, and the Service has not yet issued the permit, *Dudleya blochmaniae* ssp. *brevifolia* is protected by a Resource Protection Ordinance of the City of San Diego Municipal Code that applies to all biologically sensitive lands (§ 101.0462). Areas containing populations of *D. b.* ssp. *brevifolia* meet the municipal code definition of ''biologically sensitive lands'' because the taxon is listed under the California Endangered Species Act. Furthermore, the City of San Diego considers lands within the proposed preserve to be some of the most sensitive lands in the city (Keith Greer, Development Services, City of San Diego, pers. comm., 1996). In addition, any development proposed in the preserve area would take, at a minimum, one year to complete the building permit process (K. Greer, pers. comm., 1996) and therefore extend well

beyond the expected issuance date for the MSCP permit.

The Service will continue to monitor the status of *Dudleya blochmaniae* ssp. *brevifolia* and gather information during and after the MSCP finalization process. If information obtained by the Service indicates that the taxon is threatened or endangered, the Service will re-propose or emergency list the plant.

This notice of withdrawal is published concurrently in the Federal Register with the final rule listing four plant taxa from the maritime chaparral of southern California and Mexico, in order to resolve the listing status of all six taxa that were proposed together on October 1, 1993 (58 FR 51302). Processing the final listing decisions on these six plant taxa follows the Service's listing priority guidance published in the Federal Register on May 16, 1996 (61 FR 24722).

References Cited

City of San Diego. 1995. Neighborhood 8A precise plan/Del Mar Highlands Estates/Lorenz Parcel compromise Plan and Neighborhood 8A acquisition program. Final Environmental Impact Report.

Lane, Meredith A. 1992. New combinations in Californian *Lessingia* (Compositae: Asteraceae), Novon 2: 213–214.

Lane, Meredith A. 1993. *Lessingia* in: The Jepson Manual, Higher Plants of California, J. Hickman (ed.), University of California Press, Berkeley.

OGDEN. 1995. Multiple Species Conservation Program public review draft resource document prepared for the City of San Diego.

U.S. Fish and Wildlife Service. 1996. MSCP target plant species analysis: *Dudleya blochmaniae* ssp. *brevifolia*.

Author

The primary author of this document is Fred M. Roberts, Carlsbad Field Office (see **ADDRESSES** section).

Authority

The authority for this action is section 4(b)(6)(B)(ii) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: September 27, 1996.

John G. Rogers,

Acting Director, Fish and Wildlife Service.

[FR Doc. 96–25461 Filed 10–4–96; 8:45 am]

BILLING CODE 4310–55–P

50 CFR Part 23

RIN 1018—AD63

Export of River Otters Taken in Missouri in the 1996–97 and Subsequent Seasons

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Reopening of comment period on the proposed rule.

SUMMARY: The purpose of this notice is to advise the public of the availability of additional information that has been received and will be considered prior to the Service's decision on issuance of the Scientific Authority and Management Authority findings on the proposed export of river otters harvested in the State of Missouri. The Service may apply these findings to harvests of river otters in Missouri during the 1996–97 season and subsequent seasons, subject to the conditions applying to approved States.

DATES: The Service will consider comments received on or before October 28, 1996, in making its determination on the proposed rule.

ADDRESSES: Please send correspondence concerning the proposed rule to the Office of Scientific Authority; U.S. Fish and Wildlife Service; 4401 North Fairfax Drive, Room 750; Arlington, Virginia 22203. Comments and materials received will be available for public inspection by appointment, from 8 a.m. to 4 p.m., Monday through Friday, at the Arlington Square Building, 4401 North Fairfax Drive, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT: Scientific Authority—Dr. Marshall A. Howe, Office of Scientific Authority; phone 703–358–1708; fax 703–358–2276.

Management Authority/State Export Programs—Ms. Carol Carson, Office of Management Authority; U.S. Fish and Wildlife Service; 4401 North Fairfax Drive, Room 430; Arlington, Virginia 22203; phone 703–358–2095; fax 703–358–2281.

SUPPLEMENTARY INFORMATION: The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) regulates international trade in certain animal and plant species. Exports of animals and plants listed in Appendix II of CITES require an export permit from the country of origin. As a general rule, export permits only are issued after two conditions are met. First, the exporting country's CITES Scientific Authority must advise the permit-issuing CITES Management Authority that such exports will not be detrimental to the survival of the species. This advice is known as a ''no-detriment'' finding. Second, the Management Authority must make a determination that the animals or plants were not obtained in violation of laws for their protection. If live specimens are being exported, the Management Authority must also determine that the specimens are being shipped in a humane manner with minimal risk of injury or damage to health.

On January 5, 1984 (49 FR 590), the Service published a rule granting export approval for river otters (*Lontra canadensis*) and certain other CITES-listed species of furbearing mammals from specified States and Indian Nations and Tribes for the 1983–84 and subsequent harvest seasons. In succeeding years, approval for export of one or more species of furbearers has been granted to other States and Indian Nations, Tribes, or Reservations through the rule-making process. These approvals were and continue to be subject to certain population monitoring and export requirements. Further information on the CITES requirements and the bases for the Service's Scientific Authority and Management Authority findings, as well as a summary of the information previously received from the State of Missouri, are presented in the proposed rule published in the April 2, 1996, Federal Register (61 FR 14543).

Since the close of that proposed rule's comment period (on June 3, 1996), the Service has met with staff members of the Missouri Department of Conservation and received several documents including: (1) A graph showing the relationship between the number of licensed trappers in Missouri and the price of raccoon pelts; (2) a report on ''Ownership and Use of Traps by Trappers in the United States in 1992'' prepared for the International Association of Fish and Wildlife Agencies; (3) trapping regulations in Missouri for the 1996–97 season; (4) a report titled ''Missouri Furbearer Update, Vol. III: 1990–91''; (5) a summary of current research projects on river otters in Missouri; and (6) a portion of Missouri's Conservation Commission charter, which, among other things, stipulates that the Director of the Missouri Department of Conservation is authorized to act for the Commission on emergency matters, subject to ratification by the Commission at its next regular meeting. This includes authority for emergency closure of trapping seasons.

In addition, the Service requested updated population model scenarios based on there being no harvest season for river otters in Missouri during the 1995–96 season and using different

mortality assumptions. Furthermore, discussions have been and are being held with selected individuals concerning trapper behavior, and information obtained on the percentage of individuals trapping beaver in Missouri. The Service also is reviewing other published references including ones on the impact of market dynamics on Missouri's furbearer harvest system and on an examination of variables influencing the fur harvest in Missouri.

In addition to the information regarding Missouri since the comment period, the Service has received, will consider, and may rely upon additional information contained in letters and documents submitted by several States as part of the annual monitoring described in the January 5, 1984, Federal Register (49 FR 590), including information that was solicited in advance from the State of Tennessee.

Proposed Export Decision

As stated in the April 2, 1996, Federal Register (61 FR 14543), the Service proposes to approve exports of Missouri river otters harvested during the 1996–97 and subsequent harvest seasons, on the grounds that both Scientific Authority and Management Authority criteria have been satisfied. In case a decision is made to approve exports, the Service may issue its Scientific Authority and Management Authority findings for 1 or more years in an administrative decision document, or publish such findings in a Federal Register notice.

Comments Solicited

The Service again requests comments on these proposed findings for Missouri and the proposed rulemaking adding Missouri to the list of States approved for export of river otters (61 FR 14543). The final decision on the proposed rule will take into account comments received and any additional information received. Such consideration may lead to findings different from those presented in the proposal.

The reopened comment period on the proposed rule is issued under authority of the Endangered Species Act of 1973 as amended (16 U.S.C. 1531 *et seq.*). The author of this notification is Dr. Charles W. Dane, Office of Scientific Authority.

List of Subjects in 50 CFR Part 23

Endangered and threatened species, Exports, Imports, Treaties.

Dated: October 2, 1996.

John G. Rogers,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 96–25664 Filed 10–2–96; 3:48 pm]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 217 and 222

[Docket No. 960730211–6211–01; I.D. 072296B]

RIN 0648–AJ03

Environmental Assessment on North Atlantic Right Whale Protection

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; availability of environmental assessment.

SUMMARY: NMFS announces the availability of the Environmental Assessment (EA) on a proposed rule limiting the approach to northern right whales (*Eubalaena glacialis*).

DATES: The comment period on the proposed rule ends on November 5, 1996.

ADDRESSES: Requests for copies of the EA should be sent to Dean Wilkinson, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3226.

FOR FURTHER INFORMATION CONTACT: Dean Wilkinson at (301) 713–2322.

SUPPLEMENTARY INFORMATION: On August 7, 1996, a proposed rule was published in the Federal Register to prohibit vessel and aircraft approaches within 500 yards (460 m) of northern right whales (61 FR 41116). At that time, NMFS stated that an EA on the proposed rule was in preparation. The EA is now available. Copies of the EA or the proposed rule can be obtained from the Office of Protected Resources, NMFS (see **ADDRESSES**). The public comment period on the proposed rule will end on November 5, 1996.

Dated: October 1, 1996.

Nancy Foster,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 96–25580 Filed 10–04–96; 8:45 am]

BILLING CODE 3510–22–F

Notices

Federal Register
Vol. 61, No. 195
Monday, October 7, 1996

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Water Rights Task Force Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Forest Service announces a meeting of the Water Rights Task Force established on August 20, 1996, in accordance with the provisions of the Federal Agricultural Improvement and Reform Act of 1996, as amended. The chairman has scheduled the second meeting of the Task Force in Denver, Colorado, on October 21.

DATES: The meeting will be held October 21, 1996, from 10:30 a.m. to 5:00 p.m.

ADDRESSES: The meeting will be held at the United Airlines Red Carpet Club Conference Room at the Denver International Airport.

Send written comments to Eleanor Towns, FACA Liaison, Water Rights Task Force, c/o USDA Forest Service, MAIL STOP 1124, P.O. Box 96090, Washington, DC 20090–6090. Telephone: (202) 205–1248; Fax: (202) 205–1604.

FOR FURTHER INFORMATION CONTACT: Steve Glasser, Watershed & Air Management Staff, Telephone: (202) 205–1172; Fax: (202) 205–1096.

SUPPLEMENTARY INFORMATION: The Water Rights Task Force is composed of seven members appointed by Congress and the Secretary of Agriculture to study and make recommendations on issues pertaining to water rights. At the forthcoming meeting, the Task Force will develop a plan for carrying out its assigned responsibilities. The meeting is open to the public and time will be provided at the meeting for the public to address the Task Force; however, discussion is limited to Task Force members and Forest Service personnel. Persons who wish to bring water rights matters to the attention of the Task Force may also file written statements with the Forest Service liaison at the address listed earlier in this notice either before or after the meeting..

Notice of the establishment of the Water Rights Task Force was published in the Federal Register on September 11, 1996 (61 FR 47858). The Task Force terminates either in August of 1997 or upon submission of a final report.

Dated: October 3, 1996.

David G. Unger,

Associate Chief.

[FR Doc. 96–25755 Filed 10–4–96; 8:45 am]

BILLING CODE 3410–11–M

Willamette Provincial Interagency Executive Committee (PIEC), Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Willamette PIEC Advisory Committee will meet on Thursday, October 17, 1996. The meeting will be held at the Quality Inn; 3301 Market Street NE; Salem, Oregon 97301; phone (800) 248–6273. The meeting is scheduled to begin at 9:00 a.m. and conclude at approximately 3:00 p.m. Topics tentatively scheduled on the agenda include: (1) Province Advisory Committee (PAC) priorities during the next year, (2) Response from Adaptive Management Area on research issues raised at the August meeting, (3) Local Watershed Council and PAC relationship and roles, (4) Public forum, (5) Information sharing.

The meeting is open to the public and opportunity will be available to address the Advisory Committee during the public forum. Time allotted for individual presentations to the committee will be limited to 3–5 minutes each. Written comments are encouraged and can be submitted prior to the meeting.

FOR FURTHER INFORMATION CONTACT: For more information regarding this meeting, contact Designated Federal Official Neal Forrester; Willamette National Forest, 211 Each Seventh Avenue; Eugene, Oregon 97401; (541) 465–6924.

Dated: October 1, 1996.

Darrel L. Kenops,

Forest Supervisor.

[FR Doc. 96–25595 Filed 10–4–96; 8:45 am]

BILLING CODE 3410–11–M

Natural Resources Conservation Service

Potomac Headwaters Watershed Hardy, Hampshire, Mineral, Grant, and Pendleton Counties, WV

AGENCY: Natural Resources Conservation Service, USDA.

ACTION: Notice of a finding of no significant impact.

SUMMARY: Pursuant to Section 102(2)(c) of the National Environmental Policy Act of 1969; the Council of Environmental Quality Regulations (40 CFR Part 1500); and the Natural Resources Conservation Service Regulations (7 CFR Part 650); the Natural Resources Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Potomac Headwaters Watershed, Hardy, Hampshire, Mineral, Grant, and Pendleton Counties, West Virginia.

FOR FURTHER INFORMATION CONTACT: Roger L. Bensey, State Conservationist, Natural Resources Conservation Service, 75 High Street, Morgantown, West Virginia 26505, Telephone: 304–291–4153.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Roger L. Bensey, State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this project.

The project purpose is water quality improvement of streams in the Potomac Headwaters. The planned works of improvement include installation of animal waste storage systems, dead bird composters, livestock confinement areas, nutrient management plans, and riparian buffer zones.

The Notice of a Finding Of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various Federal, State, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting Roger L. Bensey.

No administrative action on implementation of the proposed will be taken until 30 days after the date of this publication in the Federal Register.

Roger L. Bensey,

State Conservationist.

(This activity is listed in the Catalog of Federal Domestic Assistance under No. 10.904, Watersheld Protection and Flood Prevention, and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials)

Finding of No Significant Impact for Potomac Headwaters Land Treatment Watershed Project, Hardy, Hampshire, Mineral, Grant, and Pendleton Counties, West Virginia

Introduction

The Potomac Headwaters Land Treatment Watershed Project is a federally assisted action authorized for planning under Public Law 78–534, the Flood Control Act. An environmental assessment was undertaken in conjunction with the development of the watershed plan. This assessment was conducted in consultation with local, State, and Federal agencies as well as with interested organizations and individuals. Data developed during the assessment are available for public review at the following location: U.S. Department of Agriculture, Natural Resources Conservation Service, 75 High Street, Room 301, Morgantown, West Virginia 26505.

Recommended Action

Proposed is the installation of animal waste storage systems, dead bird composters, livestock confinement improvements, nutrient management plans, and riparian buffer zones for the purpose of reducing nutrient and bacterial pollution in the Potomac River headwaters.

Effects of the Recommended Action

Improvements in animal waste management will result in decreased runoff of nutrients and bacteria to streams, improving the water quality of the project area. Proper storage and application of manure and poultry litter will not only improve water quality, but will also improve the farmers efficiencies and make the product a available for market. Installation of dead bird composters will enable more growers to manage this poultry waste product in an environmentally sound and economical means. Development of nutrient management plans will assure proper field application rates of animal waste. Installation of riparian buffer zones will reduce nutrient and bacteria runoff to streams and surface waters.

Risks of water-borne illnesses will be reduced, and the water pollution threat to fishing, boating, swimming, and tourism in the area will be lessened.

The proposed action will have little or no effect on wetlands. No adverse effects to threatened/endangered species are anticipated.

Consultation has been initiated with the State Historic Preservation Office. Should significant cultural resources be identified during implementation, they will be avoided or otherwise preserved in place to the fullest practical extent. If significant cultural resources cannot be avoided or preserved, pertinent information will be recovered before construction. If there is a significant cultural resource discovery during construction, appropriate notice will be made by NRCS to the state Historic Preservation Officer and the National Park Service. Consultation and coordination have been and will continue to be used to ensure the provisions of Section 106 of Public Law 89–665 have been met and to include provisions of Public Law 89–523, as amended by Public Law 93–291. NRCS will take action as prescribed in NRCS GM 420, Part 401, to protect or recover any significant cultural resources discovered during construction.

Alternatives

The planned action is the most practical means of reducing nutrient and bacterial pollution of streams. Because no significant adverse environmental impacts will result from installation of the measures, no other alternatives, other than the no project one, were considered.

Consultation—Public Participation

Formal agency consultation began with the initiation of the notification of the State Single Point of Contact for Federal Assistance in September 1995. Scoping meetings were held in September, October, and December 1995 and interdisciplinary efforts were used in all cases. A public meeting was held on May 2, 1996 to present the Draft Plan-Environmental Assessment to the Public and to receive comments and questions.

Specific consultation was conducted with the State Historic Preservation Officer concerning cultural resources in the watershed, and with the U.S. Fish and Wildlife Service regarding threatened/endangered species. The U.S. Geological Survey, through a cooperative agreement, conducted water sampling and testing to establish baseline water quality values.

The plan-environmental assessment was transmitted to all participating and interested agencies, groups, and individuals for review and comment on March 29, 1996.

Agency consultation and public participation to date have shown no unresolved conflicts with the implementation of the selected plan.

Conclusion

The Environmental Assessment summarized above indicates that this Federal action will not cause significant local, regional, or national impacts on the environment. Therefore, based on the above findings, I have determined that an environmental impact statement for the Potomac Headwaters Land Treatment Watershed Project is not required.

Dated: October 1, 1996.

Roger L. Bensey,

State Consvst.

[FR Doc. 96–25598 Filed 10–4–96; 8:45 am]

BILLING CODE 3410–16–M

Task Force on Agricultural Air Quality

AGENCY: Natural Resources Conservation Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Task Force on Agricultural Air Quality will meet for the first time to establish operating procedures and outline objectives. The meeting is open to the public.

DATES: The meeting will take place Friday, October 25, 1996 from 9:00 a.m. to 5:00 p.m. Written material and requests to make oral presentations should reach the Natural Resources Conservation Service on or before October 21, 1996.

ADDRESSES: The meeting will be held in the Williamsburg Room, Room 104A, in the Jamie L. Whitten Federal Building, 12th and Jefferson Drive, SW, Washington, DC. Written material and requests to make oral presentations should be sent to George Bluhm, University of California, Land, Air, Water Resources, 151 Hoagland Hall, Davis, CA 95616–6827.

FOR FURTHER INFORMATION CONTACT: George Bluhm, telephone (916) 752–1018, fax (916) 752–1552.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2.

Agenda of October 25, 1996 Meeting

(1) Welcome by Task Force Chair Paul Johnson.
(2) Remarks by George Bluhm, Designated Agency Official
(3) Introduction of members.

(4) Establish operating procedures and outline objectives.
(5) As time allows, other issues brought up by the public or Task Force members.
(6) Set date and location for next meeting.

Procedural

This meeting is open to the public. At the discretion of the Chairman, members of the public may present oral presentations during the October 25, 1996 meeting. Persons wishing to make oral presentations at the October 25, 1996 meeting should notify George Bluhm, Designated Agency Official, no later than October 21, 1996. If a person submitting material would like a copy distributed to each member of the committee in advance of the meeting, that person should submit 25 copies to George Bluhm no later than October 21, 1996.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact George Bluhm as soon as possible.

Dated: September 30, 1996.

Richard L. Duesterhaus,

Deputy Chief, Science and Technology.

[FR Doc. 96–25478 Filed 10–4–96; 8:45 am]

BILLING CODE 3014–16–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–834–802, A–835–802, A–844–802]

Agreement Suspending the Antidumping Investigation on Uranium from Kazakstan, Kyrgyzstan and Uzbekistan

AGENCY: Import Administration, International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of Price Determination on Uranium from Kazakstan, Kyrgyzstan and Uzbekistan.

SUMMARY: Pursuant to Section IV.C.1. of the antidumping suspension agreement on uranium from Kazakstan, Kyrgyzstan, and Uzbekistan, the Department of Commerce (the Department) calculated a price for uranium of $15.78/lb. On the basis of this price, the export quota for uranium pursuant to Section IV.A. of the Kazakstani agreement, as amended on March 27, 1995, is 700,000 lbs for the period October 1, 1996, through March 31, 1996. The export quota for uranium pursuant to Section IV.A. of the Uzbek agreement, as amended on October 13, 1995, is 940,000 lbs for the period October 13, 1996, through October 12, 1997. Exports pursuant to other provisions of these agreements are not affected by this price.

EFFECTIVE DATE: October 1, 1996.

FOR FURTHER INFORMATION CONTACT: Alexander Braier or Yury Beyzarov, Office of Agreements Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Ave., NW, Washington, DC 20230; telephone: (202) 482–3818 or (202) 482–2243, respectively.

PRICE CALCULATION:

Background

Section IV.C.1. of the antidumping suspension agreements on uranium from Kazakstan, Kyrgyzstan, and Uzbekistan specifies that the Department will issue its observed market price on October 1, 1996, and use it to determine the quota applicable to exports from Kazakstan during the period October 1, 1996, to March 31, 1997 and from Kyrgyzstan and Uzbekistan during the period of October 13, 1996, to October 12, 1997. Consistent with the February 22, 1993, letter of interpretation, the Department provided interested parties with the preliminary price determination on September 18, 1996.

Calculation Summary

Section IV.C.1. of these agreements specifies how the components of the market price are reached. In order to determine the spot market price, the Department utilized the monthly average of the Uranium Price Information System Spot Price Indicator (UPIS SPI) and the weekly average of the Uranium Exchange Spot Price (Ux Spot). In order to determine the long-term market price, the Department utilized the weighted-average long-term price as determined by the Department on the basis of information provided by market participants and a simple average of the UPIS U.S. Base Price for the months in which there were new contracts reported.

The Department's letters to market participants provided a contract summary sheet and directions requesting the submitter to report his/her best estimate of the future price of merchandise to be delivered in accordance with the contract delivery schedules (in U.S. dollars per pound U_3O_8 equivalent). Using the information reported in the proprietary summary sheets, the Department calculated the present value of the prices reported for any future deliveries assuming an annual inflation rate of 2.52 percent, which was derived from a rolling average of the annual GDP Implicit Price Deflator index from the past four years. The Department used the base quantities reported on the summary sheet for the purpose of weight-averaging the prices of the long-term contracts submitted by market participants. The Department then calculated a simple average of the UPIS U.S. Base Price and the long-term price as determined by the Department.

Weighting

The Department used the average spot and long-term volumes of U.S. utility and domestic supplier purchases, as reported by the Energy Information Administration (EIA), to weight the spot and long-term components of the observed price. In this instance, we have used purchase data from the period 1992–1995. During this period, the spot market accounted for 73.74 percent of total purchases, and the long-term market for 26.26 percent.

As in previous determinations, the Department used the Energy Information Administration's (EIA) *Uranium Industry Annual* to determine the available average spot- and long-term volumes of U.S. utility purchases. We have updated the data to reflect the period 1992 through 1995. The EIA has withheld certain contracting data from the public versions of the *Uranium Industry Annual 1993*, *Uranium Industry Annual 1994*, and the *Uranium Industry Annual 1995* because this data was business proprietary. The EIA, however, provided this data to the Department and the Department has used it to update its weighting calculation. Accordingly, it may only be released under Administrative Protective Order.

Calculation Announcement

The Department determined, using the methodology and information described above, that the observed market price is $15.78. This reflects an average spot market price of $16.28, weighted at 73.74 percent, and an average long-term contract price of $14.38, weighted at 26.26 percent. The decrease in the observed market price from our preliminary determination reflects the correction of clerical errors, as discussed below, and our inclusion in the calculation of two contracts that were inadvertently omitted from our preliminary price calculation. Since this price is between $15.00/lb and $15.99/lb expressed in Appendix A of the

suspension agreement with Kazakstan, as amended, Kazakstan receives a quota of 700,000 lbs for the period October 1, 1996, to March 31, 1997. The suspension agreement with Uzbekistan, as amended, specifies that Uzbekistan shall have access to its Appendix A quota of 940,000 lbs for the period of October 13, 1996 to October 12, 1997, provided that the calculated price is at or above $12.00 per pound.

Comments

Consistent with the February 22, 1993, letter of interpretation, the Department provided interested parties the preliminary price determination for this period on September 18, 1996. One interested party submitted comments.

UPIS Index Used

Comment 1: The Ad Hoc Committee of Domestic Uranium Producers (the producers) request that the Department correct a minor data error in its spot price segment of the calculation. According to the producers, the Department apparently inadvertently used the UPIS Short-Term Price Indicator data rather than the UPIS Spot Price Indicator data, which is consistent with previous calculations.

Department's Position: The Department agrees with the producers and has corrected the data error.

Long Term Contracts

Comment 2: The producers indicated that the Department made a clerical error in its reporting of the volume of a long term contract (contract number 1) as the Department apparently had two different volumes listed for the same contract.

Department's Position: The Department agrees with the producers and has corrected the error in question.

After the analysis of the above comments, the Department has determined that the observed market price for uranium is $15.78/lb. The Department invites parties to provide pricing information for use in the next price determination. Any such information should be provided for the record and should be submitted to the Department by March 5, 1997.

Dated: October 2, 1996.

Joseph A. Spetrini,

Deputy Assistant Secretary for Antidumping Countervailing Duty—Group III.

[FR Doc. 96–25647 Filed 10–4–96; 8:45 am]

BILLING CODE 3510–DS–P

[C–122–404]

Live Swine from Canada; Final Results of Countervailing Duty Administrative Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Final Results of Countervailing Duty Administrative Reviews.

SUMMARY: On May 29, 1996, the Department of Commerce (the Department) published in the Federal Register its preliminary results of three administrative reviews of the countervailing duty order on live swine from Canada. We have completed these reviews and determine the net subsidy to be Can$0.0601 per kilogram for the period April 1, 1991 through March 31, 1992, Can$0.0613 per kilogram for the period April 1, 1992 through March 31, 1993, and Can$0.0106 per kilogram for the period April 1, 1993 through March 31, 1994. We will instruct the U.S. Customs Service to assess countervailing duties as detailed in the *Final Results of Reviews* section of this notice.

EFFECTIVE DATE: October 7, 1996.

FOR FURTHER INFORMATION CONTACT: Stephanie Moore or Cameron Cardozo, Office of CVD/AD Enforcement, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Background

On May 29, 1996, the Department published in the Federal Register the preliminary results of three administrative reviews of the countervailing duty order on live swine from Canada (61 FR 26879). We invited interested parties to comment on the preliminary results. On June 3, 1996, the Canadian Pork Council requested an extension of the time limit for submission of the case briefs from June 28, 1996 until July 8, 1996. We granted this request and on July 8, 1996, case briefs were submitted by the National Pork Producers' Council, petitioners, and by the Government of Canada (GOC), the Government of Quebec (GOQ), and the Canadian Pork Council (CPC), respondents. Rebuttal briefs were submitted by petitioners, the GOC, the GOQ, and the CPC. On June 13, 1996, the GOQ requested a public hearing. The Department denied the request for the hearing because the request was untimely. The Department has now completed these administrative reviews in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

The periods covered by these administrative reviews are April 1, 1991 through March 31, 1992, April 1, 1992 through March 31, 1993, and April 1, 1993 through March 31, 1994. These reviews were conducted on an aggregate basis and involve 43 programs.

Applicable Statute and Regulations

The Department is conducting these administrative reviews in accordance with section 751(a) of the Act. Unless otherwise indicated, all citations to the statute and to the Department's regulations are in reference to the provisions as they existed on December 31, 1994. However, references to the Department's *Countervailing Duties; Notice of Proposed Rulemaking and Request for Public Comments,* 54 FR 23366 (May 31, 1989) (*Proposed Regulations*), are provided solely for further explanation of the Department's countervailing duty practice. Although the Department has withdrawn the particular rulemaking proceeding pursuant to which the *Proposed Regulations* were issued, the subject matter of these regulations is being considered in connection with an ongoing rulemaking proceeding which, among other things, is intended to conform the Department's regulations to the Uruguay Round Agreements Act. *See* 60 FR 80 (Jan. 3, 1995).

Scope of the Reviews

On August 29, 1996, the *Final Results of Changed Circumstances Countervailing Duty Administrative Review, and Partial Revocation* were published (61 FR 45402), in which we revoked the order, in part, effective April 1, 1991, with respect to slaughter sows and boars and weanlings from Canada, because this portion of the order was no longer of interest to domestic interested parties. As a result, the merchandise now covered by the order and by these administrative reviews is live swine except U.S. Department of Agriculture certified purebred breeding swine, slaughter sows and boars and weanlings (weanlings are swine weighing up to 27 kilograms or 59.5 pounds). The merchandise subject to the order is classifiable under the *Harmonized Tariff Schedule* (HTS) item numbers 0103.91.00 and 0103.92.00. The HTS item numbers are provided for convenience and Customs purposes. The written description remains dispositive.

Calculation Methodology for Assessment and Cash Deposit Purposes

For each review period, we calculated the net subsidy on a country-wide basis by first calculating the subsidy rate for each province subject to the administrative review. We then weight-averaged the rate received by each province using as the weight the province's share of total Canadian exports to the United States of subject merchandise. We then summed the individual provinces' weighted-average rates to determine the subsidy rate from all programs benefitting exports of the subject merchandise to the United States. In prior proceedings, a separate rate was calculated for sows and boars and for all other live swine. Due to the partial revocation with respect to slaughter sows and boars, we are only calculating a rate for live swine.

Analysis of Programs

Based upon our analysis of the questionnaire responses, our verification, and written comments from the interested parties, we determine the following:

I. Programs Conferring Subsidies

1. Feed Freight Assistance

In the preliminary results, we found that this program conferred countervailable benefits on the subject merchandise. We received no comments on our preliminary results, however, we found an error in our calculations which we have corrected. *See Calculation Memorandum* on file in the Central Records Unit, Room B099, of the Main Commerce Building. On this basis, the net subsidies for this program are Can$0.0006 per kilogram for the 1991–92 review period, Can$0.0004 per kilogram for 1992–93 review period, and Can$0.0004 per kilogram for the 1993–94 review period.

2. National Tripartite Stabilization Program (NTSP)

In the preliminary results, we found that this program conferred countervailable benefits on the subject merchandise. Our analysis of the comments submitted by the interested parties, summarized below, has not led us to change our findings from the preliminary results. On this basis, the net subsidies for this program are Can$0.0508 per kilogram for the 1991–92 review period and Can$0.0578 per kilogram for 1992–93 review period. The program was not used during the 1993–94 review period.

3. Quebec Farm Income Stabilization Insurance Program (FISI)

In the preliminary results, we found that this program conferred countervailable benefits on the subject merchandise. Our analysis of the comments submitted by the interested parties, summarized below, has not led us to change our findings from the preliminary results. On this basis, the net subsidies for this program are Can$0.0050 per kilogram for the 1991–92 review period, Can$0.0001 per kilogram for the 1992–93 review period, and Can$0.0003 per kilogram for the 1993–94 review period.

4. British Columbia Farm Income Insurance Program (FIIP)

In the preliminary results, we found that this program conferred countervailable benefits on the subject merchandise. We received no comments on our preliminary results and our findings remain unchanged in these final results. On this basis, the net subsidies for this program are less than Can$0.0001 per kilogram for the 1992–93 review period, and Can$0.0004 for the 1993–94 review period. British Columbia did not export live swine to the United States during the 1991–92 review period.

5. Saskatchewan Hog Assured Returns Program (SHARP)

In the preliminary results, we found that this program conferred countervailable benefits on the subject merchandise. Our analysis of the comments submitted by the interested parties, summarized below, has led us to change our findings from the preliminary results. We are adding interest accrued during the ninth review period to the amount of the deficit written off to calculate the amount of the SHARP grant. Also, in line with our preference to use commercial lending rates rather than government lending rates, we recalculated the benefit from the SHARP grant by using the monthly average medium-term corporate bond rate from the *Bank of Canada Review* as the discount rate in our allocation methodology. On this basis, the net subsidies for this program are Can$0.0010 per kilogram for the 1991–92 review period, Can$0.0007 per kilogram for the 1992–93 review period, and Can$0.0055 per kilogram for the 1993–94 review period.

6. Alberta Crow Benefit Offset Program (ACBOP)

In the preliminary results, we found that this program conferred countervailable benefits on the subject merchandise. Our analysis of the comments submitted by the interested parties, summarized below, has not led us to change our findings from the preliminary results. On this basis, the net subsidies for this program are Can$0.0023 per kilogram for the 1991–92 review period, Can$0.0019 per kilogram for the 1992–93 review period, and Can$0.0017 per kilogram for the 1993–94 review period.

7. Alberta Livestock and Beeyard Compensation Program

In the preliminary results, we found that this program conferred countervailable benefits on the subject merchandise. We received no comments on our preliminary results and our findings remain unchanged in these final results. On this basis, the net subsidy for this program is less than Can$0.0001 per kilogram for the 1991–92, 1992–93, and 1993–94 review periods.

8. Ontario Rabies Indemnification Program

In the preliminary results, we found that this program conferred countervailable benefits on the subject merchandise. We received no comments on our preliminary results and our findings remain unchanged in these final results. On this basis, the net subsidy for this program is less than Can$0.0001 per kilogram for the 1991–92, 1992–93, and 1993–94 review periods.

9. Ontario Livestock and Poultry and Honeybee Compensation Program

In the preliminary results, we found that this program conferred countervailable benefits on the subject merchandise. We received no comments on our preliminary results and our findings remain unchanged in these final results. On this basis, the net subsidy for this program is less than Can$0.0001 per kilogram for the 1991–92, 1992–93, and 1993–94 review periods.

10. Saskatchewan Livestock Investment Tax Credit

In the preliminary results, we found that this program conferred countervailable benefits on the subject merchandise. We received no comments on our preliminary results and our findings remain unchanged in these final results. On this basis, the net subsidy for this program is Can$0.0002 per kilogram for the 1991–92, 1992–93, and 1993–94 review periods.

11. Saskatchewan Livestock Facilities Tax Credit Program

In the preliminary results, we found that this program conferred countervailable benefits on the subject merchandise. We received no comments on our preliminary results and our findings remain unchanged in these final results. On this basis, the net subsidy for this program is Can$0.0001 per kilogram for the 1991–92, 1992–93, and 1993–94 review periods.

12. *Saskatchewan Interim Red Meat Production Equalization Program*

In the preliminary results, we found that this program conferred countervailable benefits on the subject merchandise due to allegations of new subsidies by the petitioner during the 1992–93 review period. We received no comments on our preliminary results and our findings remain unchanged in these final results. On this basis, the net subsidies for this program are Can$0.0002 per kilogram for the 1992–93 review period and Can$0.0021 per kilogram for the 1993–94 review period.

13. Ontario Export Sales Aid Program

In the preliminary results, we found that this program conferred countervailable benefits on the subject merchandise. We received no comments on our preliminary results and our findings remain unchanged in these final results. On this basis, the net subsidy for this program is less than Can$0.0001 per kilogram for the 1991–92 and 1993–94 review periods. The program was not used during the 1992–93 review period.

II. Programs Found Not to Confer Subsidies

In the preliminary results, we found the following programs to be non-countervailable:

A. Canada/British Columbia Agri-Food Regional Development Subsidiary Agreement;

B. Canada/Manitoba Agri-Food Development Agreement;

C. Canada/Quebec Subsidiary Agreement on Agri-Food Development;

D. Net Income Stabilization Accounts (NISA);

E. Saskatchewan Livestock Cash Advance Program;

F. Ontario Farm Tax Rebate Program;

G. Prince Edward Island Pro Pork Assistance Program;

H. Cash Flow Enhancement Program.

Our analysis of the comments submitted by the interested parties, summarized below, has not led us to change our findings from the preliminary results.

III. Programs Found Not to be Used

In the preliminary results, we found that the producers and/or exporters of the subject merchandise did not apply for or receive benefits under the following programs:

A. Agricultural Products Board Program;

B. Federal Atlantic Livestock Feed Initiative (New Brunswick, Newfoundland, Nova Scotia, and Prince Edward Island);

C. Western Diversification Program;

D. British Columbia Special Hog Payment Program;

E. New Brunswick Development Act—Swine Assistance Program;

F. New Brunswick Livestock Incentives Program;

G. New Brunswick Swine Assistance Policy on Boars;

H. New Brunswick Swine Industry Financial Restructuring Program;

I. Newfoundland Farm Products Corporation–Hog Price Support;

J. Newfoundland Weanling Bonus Incentive Policy;

K. Nova Scotia Improved Sire Policy;

L. Ontario Bear Damage to Livestock Compensation Program; and

M. Ontario Swine Sales Assistance Policy.

Our analysis of the comments submitted by the interested parties, summarized below, has not led us to change our findings from the preliminary results.

IV. Programs Found to be Terminated

In the preliminary results, we found the following programs to be terminated and that no residual benefits were provided during the review periods:

A. New Brunswick Hog Price Stabilization Plan;

B. Canada/Alberta Swine Improvement Program Study;

C. Canada/Ontario Western Agribition Livestock Transportation Assistance Program;

D. Canada/Ontario Stabilization Plan for Hog Producers;

E. Alberta Red Meat Interim Insurance;

F. Ontario Livestock Improvement Program for Northern Ontario;

G. Ontario Pork Industry Improvement Plan;

H. Prince Edward Island Interest Payments on Assembly Yard Loan; and

I. Prince Edward Island Swine Incentive Policy.

Our analysis of the comments submitted by the interested parties, summarized below, has not led us to change our findings from the preliminary results.

Analysis of Comments

Comment 1: Petitioners argue that the Department should revise its preliminary determination that NISA's farm-fed grain provision does not provide a countervailable benefit to hog producers. They state that the farm-fed provision is a discrete and independent sub-program of NISA and, thus, the Department should analyze NISA's countervailability in the narrower context of the farm-fed grain provision. According to petitioners, such an approach is justified because hog farmers would be ineligible for NISA assistance without this provision. Therefore, the farm-fed grain component of the broader NISA program is sufficiently unique and circumscribed to warrant consideration on an independent basis. Petitioners maintain that this approach is consistent with the Department's analysis of the countervailability of particular subsidies on a sub-program basis in *Small Diameter Circular Seamless Carbon and Alloy Steel Standard, Line and Pressure Pipe from Italy,* 60 FR 31992 (June 19, 1995) (*Italian Pipe*).

The petitioners contend that the farm-fed provision is countervailable because it provides a direct transfer of funds to hog producers and it expressly limits eligibility for the program to livestock producers and hence, is *de jure* specific. Also, the NISA farm-fed grain provision is virtually identical to the ACBOP program, which the Department has recognized as a countervailable subsidy. According to petitioners, both programs share the same basic goal of subsidizing hog farmers who also grow grains. The record contains no compelling legal or factual basis for treating ACBOP as countervailable while allowing NISA to escape the purview of U.S. countervailing duty law. Finally, petitioners state that the farm-fed grain provision constitutes an express mechanism for subsidizing hog farmers by providing these farmers benefits that they otherwise would not be entitled to receive.

The GOC and the CPC counter that the Department properly concluded that NISA is not specific and that petitioners have not challenged this determination. The GOC and the CPC contend that the farm-fed provision cannot be examined separately because of the whole farm nature of the NISA program. Contributions are based on the entire farm's total net sales of all eligible products, and withdrawals are based on overall farm income rather than the income of particular products. Thus, NISA-eligible products cannot be examined separately for purposes of

calculating NISA withdrawals. The purpose of the provision is to provide the same coverage to grain farmers that feed some of their grain to livestock and to grain farmers that sell their grain and thus generate sales of an eligible product. By providing this coverage, according to respondents, NISA avoids creating an artificial incentive to farmers to sell their grain rather than feed it on-farm. Thus, any benefit the farm-fed provision may provide to farmers who produce hogs and grow grain is like any other benefit farmers may receive on NISA-eligible products and is, thus, not countervailable.

The GOC and the CPC continue that, contrary to the petitioners' ''sub-program'' theory, the record actually shows that the feed equivalent is one line in the NISA eligible net sales calculation. This one line is blended into a single total eligible net sales number on which the matchable producer contributions are calculated. The GOC and the CPC state that there simply is no separate existence of the farm-fed equivalent provision as a NISA ''sub-program'' in any respect. However, even if the Department were to accept the petitioners' argument, they argue that NISA and its feed equivalent would have to be considered a single program. NISA makes all farmers eligible, offers only one type of benefit, one set of eligibility requirements, one administering agency, one legislative source, and no administrative discretion. Therefore, NISA must be examined as a whole and found not specific.

Finally, the GOC and the CPC claim that the petitioners' attempt to compare the farm-fed grain provision to ACBOP is also incorrect. ACBOP is directed only at purchasers and producers of feed grain and its benefits are tied to grain purchases and actual use in livestock feed by livestock producers. NISA is a program for producers of numerous products and whose ''whole farm'' concept eliminates any link between contributions or withdrawals, on the one hand, and a farmer's purchases of one input in production, such as grain, on the other.

Department's Position: We disagree with the petitioners that the farm-fed grain provision of NISA should be analyzed separately for purposes of our countervailing duty analysis. Rather than a separate sub-component of the NISA program, the farm-fed grain provision is an integral part of the NISA program designed to equalize treatment of farm-fed grains and marketed grains. There are no separate eligibility requirements for receiving NISA assistance under the farm-fed grain provision. Eligible contributions under the farm-fed provision are represented by a single line item in the NISA eligible net sales calculation, which includes net sales of all other NISA-eligible products. All of these net sales of eligible products are combined into a single total eligible net sales number on which the matchable producer and government contributions are calculated. In sum, calculations of benefits under the farm-fed provision are indistinguishable from the other NISA calculations.

Moreover, the NISA farm-fed grain provision is not like Law 675 which we analyzed in *Italian Pipe*. In that case, Law 675 was a single law that encompassed six separate and discrete programs that provided benefits to particular industries. Each program had distinct purposes, types of benefits, application and approval procedures, and administration. *Italian Pipe*, 60 FR 31995–96. The NISA program has one purpose, one type of benefit, one set of eligibility requirements, and one administering agency. For these reasons, we continue to analyze the countervailability of the farm-fed provision within the context of the overall NISA program.

Further, we do not agree that NISA's farm-fed provision is virtually identical to the ACBOP program. ACBOP was found *de jure* specific because it is limited to and directly benefits only purchasers and producers of feed grain (*Live Swine from Canada; Final Results of Countervailing Duty Administrative Reviews*, 48 FR 10410 (March 12, 1991)). Because hog producers benefit from a program found to be *de jure* specific, we have countervailed those benefits under ACBOP in our administrative reviews of this order. In the case of NISA, we have found that the program is not *de jure* specific because the legislation does not expressly limit the availability of the program. Furthermore, we have found that NISA is not *de facto* specific because a large majority and wide variety of all agricultural products are covered, there is no evidence of dominant use or disproportionality of benefits by a specific enterprise or industry, and there is almost no government discretion in conferring benefits. Because we have determined that NISA, including the farm-fed grain provision, is a single program, we do not need to address the issue of specificity at the level of the farm-fed grain provision.

Comment 2: Petitioners argue that in calculating the NISA farm-fed grain benefit, the Department should include Farm Support and Adjustment Measures (FSAMs) funds as part of the government's contribution into the NISA program. According to petitioners, since FSAMs reflect federal incentive contributions and federal bonuses for early enrollment in NISA, they are an integral part of the total benefits paid out under NISA. Also, FSAM contributions equaled more than half of total federal government contributions to the NISA program. Yet, in the calculations of estimated NISA benefits submitted by the GOC, FSAM funds were not included. Petitioners state that by not including FSAM contributions, the GOC's calculation fails to reflect the true amount of benefits accruing to hog producers.

Respondents counter that the petitioners are inconsistent when they argue that a line item in the NISA calculation, the farm-fed grain provision, is a separate program, and then argue that FSAMs, which in the respondent's view is a separate program, is one and the same with NISA. In any case, respondents state that FSAMs are non-specific whether viewed as a separate program or as part of NISA. FSAMs were a temporary and transitional measure to assist in getting the NISA and GRIP programs off the ground. As a separate program, FSAMs provided benefits to all of the same products covered by NISA in its first year of operation. Therefore, respondents argue that FSAMs are also non-specific. On the other hand, according to respondents, if FSAMs are integral to the NISA program, then FSAMs are still non-specific since NISA is not specific.

Department's Position: FSAM benefits are indistinguishable from those provided by NISA. Although provided for under additional legislation, FSAMs can only deliver benefits through a previously established program, NISA. Under the NISA program, a farmer can make deposits, up to 2 percent of net eligible sales, into an individual savings account and receive matching government deposits, up to 1 percent of net sales each from the provincial and federal governments. As we stated in our verification report, through FSAMs the federal government contributed to the NISA program in excess of this 1 percent of net sales during NISA's initial year of operation. As a result, more funding was available to farmers for withdrawals from their NISA accounts. However, since we have determined that NISA is not specific, any additional benefits provided under NISA via FSAMs are not countervailable.

Comment 3: The petitioners state that the GOC has understated the NISA farm-fed grain benefit for the eighth review

period. According to petitioners, given the verified data pertaining to the seventh review, the Department should reject the GOC's information and calculate farm-fed NISA benefits for the eighth and ninth review using adjusted data from the seventh review.

The GOC responds that the farm-fed grain calculations provided are admittedly complex and NISA's whole-farm approach makes it impossible to account for payments on a product basis. Thus, any calculation methodology necessarily will involve a number of allocations and components. In any case, because NISA is non-specific, the GOC maintains that delving back into these calculations in not necessary.

Department's Position: Since the Department has determined that NISA is not countervailable, the issue of the accuracy of the GOC's NISA benefit calculations is moot.

Comment 4: The GOC argues that the Department's preliminary determination that FIPA does not constitute a single program does not reflect any reasonably clear articulation of the standard to be applied. According to the GOC, the Department's preliminary determination mentions at least eight factors, but does not explicitly identify which of the eight factors are important, which are reflective of past Department decisions, or the priority by which the factors should be considered. The GOC continues that the agency must articulate with reasonable clarity the reasons for a decision, including the standards being applied and the weight accorded to significant facts. As a result, the GOC requests the Department to formulate an appropriate ''single program'' standard based on factors relevant to that inquiry and to redetermine whether FIPA is a single program under that standard.

The petitioners reply that the agency's single program analysis is not dictated by statute or regulation, but rather, constitutes a simple factual analysis undertaken by the agency in its role as decision maker. According to petitioners, when neither the statute nor the regulations prescribe a particular methodology to be used, the agency's decision will be considered a reasonable exercise of discretion as long as it recognizes and considers the relevant facts. In this case, the Department's explanation clearly references and discusses all of the evidence relevant to its separate treatment of the FIPA programs.

Department's Position: Neither the countervailing duty statute nor regulations mandate a specific standard to be used when determining whether a program under review should be treated as a single program or several programs. Under these circumstances, the Department has discretion and must base its determination on a reasonable interpretation of the facts on the record. See *Hercules* v. *United States*, 673 F. Supp. 454, 463 (CIT 1987). The record shows that we extensively analyzed the information submitted by the GOC, as well as our determinations in prior cases, in reaching our determination that we should examine the components of FIPA as separate programs. (*See* Memorandum on Farm Income Protection Act, to Barbara E. Tillman from CVD team dated April 13, 1994, which is on file in the Central Records Unit, Room B099, of the Main Commerce Building, *FIPA Memorandum*.) The *FIPA Memorandum* shows that the Department analyzed in great detail the legislation, structure, and operation of FIPA and its component parts and compared this set of facts with previous decisions of the Department. Whether there is one program or multiple programs is a question of fact, not a legal analysis. Thus, the question can only be addressed through examination of the facts of record. Although a comparison of the facts in this case with the facts of other cases in which we examined the same issue may be part of that analysis, these are case-by-case factual findings. The *FIPA Memorandum* clearly explains the primary facts leading to our conclusion that FIPA encompasses several separate programs: (1) the FIPA legislation authorizes agreements between the GOC and the provincial governments to protect the income of agricultural producers, (2) the federal/provincial agreements that established the operations of NISA, Gross Revenue Insurance Program (GRIP), Crop Insurance, and NTSPs retain significant discretion with respect to FIPA's statutory authority in identifying the type of beneficiary under each program, delineating administrative procedures, and setting up funding commitments among the participants, and (3) NISA, NTSP, GRIP and Crop Insurance have separate and different eligibility criteria and application procedures.

The GOC does not dispute those facts but believes that the Department should have reached a different conclusion given other facts. Specifically, the GOC believes that a ''single legislative enactment'' should assume an elevated role in our analysis. We disagree (see *Department's Position* on *Comment 5*) and continue to find that the facts support our conclusion that these are separate programs. *Matsushita Elec. Co.* v. *United States*, 750 F.2d 927, 933 (Fed. Cir. 1984) (the possibility of two inconsistent conclusions does not warrant reversal of the agency's reasonable determination).

Comment 5: The GOC proposes a new standard for the single program inquiry which includes three prongs: whether the programs in question stem from a single legislative enactment, whether the enactment contains sufficient substantive detail to define the programs with reasonable certainty, and whether the constituent programs involve at least some common administrative oversight. By this standard, the GOC maintains that FIPA should be judged to be a single program.

The petitioners respond that this ''single legislative enactment'' standard contravenes the basic purpose of U.S. countervailing duty law since a critical component of the subsidy analysis is whether a program, as *applied*, provides a specific benefit to an industry. Moreover, even under the application of this standard, FIPA is not a single program since, state petitioners, FIPA did not create the assistance provided under NTSP and Crop Insurance, but attached to these pre-existing programs the same label associated with the newly created GRIP and NISA programs. Accepting the GOC's argument would mean that virtually every time a government enacts a comprehensive initiative to provide assistance to an industry, the Department would be precluded from examining the elements of that initiative on an individual basis.

Department's Position: We disagree with the GOC. As we explained in *Department's Position on Comment 4*, there is no legal or regulatory requirement that the Department develop a ''single program standard.'' In the Department's view, because of the complexity and variety of subsidy programs, a case-by-case analysis represents a more reasonable approach than the development of a standardized test for purposes of this single program analysis. *See e.g., Geneva Steel* v. *United States*, 914 F. Supp. 563, 593 (CIT 1996) (''Commerce is afforded considerable leeway in exacting and applying methodologies to interpret the countervailing duty statute.'') In any case, the GOC's proposed ''three-pronged standard'' would not permit a full analysis of whether there are multiple programs or a single program. A complete analysis requires examining the details of the program—specific purposes of the component parts, eligibility requirements, types of benefits, the administering agency, application and approval procedures, and any administrative discretion.

Apparently, the GOC also recognizes these additional factors since, in its rebuttal argument in *Comment 1,* it argues that NISA and its farm-fed grain provision are one program because NISA offers only one type of benefit, one set of eligibility requirements, one administering agency, one legislative source, and no administrative discretion. The Department has also examined all of these factors with respect to FIPA (see FIPA Memorandum) and determined, based on the facts on the record, that FIPA's components should be treated as separate programs.

Comment 6: The GOC argues that the preliminary determination does not meaningfully distinguish FIPA from prior cases in which the Department has found a single program in a complex, multi-faceted statute. The GOC cites *Italian Steel, Mexican Roses* and *Malaysian Wire Rod* [1] as precedent in which the Department treated a complex set of laws as a single program. In those cases, the programs provided different types of benefits and delivered them in different forms. By contrast, according to the GOC, the FIPA options provide far more consistent benefits, namely income stabilization, than in the above cases. Furthermore, the GOC argues that in the sixth review of this order, the Department determined that the eight revenue insurance options under the NTSP constituted a single program. Similarly, all FIPA options derive from a single legislative enactment and provide one type of assistance, income stabilization. The GOC concludes that these parallels lead to the conclusion that FIPA is also a single program.

According to petitioners, the GOC's attempts to place FIPA within the context of the analysis used in *Mexican Roses* and in the sixth live swine review are unavailing. For example, the Court reviewing the Department's decision in *Mexican Roses* stated that ''[p]rograms bestowing benefits on different enterprises or industries for different policy reasons should not escape countervailability simply because the programs are loosely grouped under one heading, here FIRA.'' 743 F. Supp. at 880. And, regarding the Department's finding with respect to NTSP, the GOC ignores that, without the individual Tripartite agreements that comprise NTSP, the program would not exist. By contrast, petitioners state that FIPA would clearly continue to exist even if one of its individual component programs did not. Similarly, the NTSP agreements operate the same way for each benefiting commodity, while there are clear differences in the operation of the four FIPA components.

Department's Position: We disagree with the GOC. In the *FIPA Memorandum,* we clearly stated why we considered the fact pattern in *Malaysian Wire Rod* and *Italian Steel* as dissimilar to the fact pattern regarding FIPA. In both cases, an overarching program consisted of several components. Companies could only obtain benefits from the component programs by following the application and eligibility requirements established at the overarching program level. Once eligible and approved under the overarching program, there was no restriction on the type of benefits that could be received under the program components. FIPA, on the other hand, allows the federal/provincial agreements to establish different application and eligibility procedures. There is no general eligibility under FIPA, which automatically confers eligibility under NISA, NTSP, GRIP, and crop insurance. Agricultural producers subject to a NTSP agreement are ineligible for either NISA or GRIP unless granted eligibility under the relevant NTSP federal/provincial agreement. Furthermore, GRIP and crop insurance do not cover hogs or other livestock because their acreage-based calculations are inherently inapplicable to livestock.

Also, the GOC's cite to *Mexican Roses* is not persuasive support for finding FIPA a single program. In that case, the Department reaffirmed its position that the agricultural sector constitutes more than a single group of industries for purposes of determining specificity and then found that loans provided to Mexican flower producers granted under the Funds Established with Relationship to Agriculture (FIRA) were not specific since they were not targeted to exports, nor provided to a specific industry or group of industries. Since Mexican flower producers only used loans available under FIRA, we had no need to address whether the other benefits available under FIRA constituted one or several programs. We found that the assistance used by flower growers was provided to more than a specific enterprise or industry or group thereof. Also, in reviewing this case, the CIT stated that individual programs should not escape countervailability simply because they are loosely grouped under one heading. *See Roses, Inc.* v. *United States* 743 F. Supp. 870, 880 (CIT 1990).

We have treated the eight revenue insurance plans that comprise NTSP as one program because, unlike FIPA, we determined that the relevant legislation established a framework for providing a single type of benefit for a single purpose. Each of the insurance plans offered the same types of benefits, had the same application procedures, and the same funding mechanisms. *Live Swine from Canada; Final Results of Countervailing Duty Administrative Review,* 59 FR 12243 (March 16, 1994) (*Swine VI*) at 12245. Likewise, as even the GOC acknowledges, we determined that NISA and its farm-fed grain provision were one program since they offered one type of benefit, one set of eligibility requirements, one administering agency, one legislative source, and no administrative discretion.

As we explained in the *FIPA Memorandum,* we determined that the facts pertaining to the FIPA programs were more similar to several cases where the Department determined to treat a program as several components, *e.g. Canadian Groundfish, Thai Bearings,* and *Canadian Magnesium.*[2] For instance, the facts in the FIPA analysis are similar to *Canadian Groundfish* where Economic and Regional Development Agreements (ERDAs) provided the legal basis for departments of the federal and provincial governments to cooperate in the establishment of economic development programs. Pursuant to the ERDA, subsidiary agreements were signed which established programs, delineated administrative procedures and set up relative funding commitments of the federal and provincial governments. We determined that the ERDAs acted as umbrella legislation to achieve the broad goal of economic development whereas the subsidiary agreements actually provided for the operation and administration of the programs. Therefore, for purposes of analyzing specificity, we examined each subsidiary agreement as a separate program, which the CIT affirmed. *See*

[1] *Final Affirmative Countervailing Duty Determination and Countervailing Duty Order on Carbon Steel Wire Rod from Malaysia* (53 FR 13303; April 22, 1988); *Final Affirmative Countervailing Duty Determinations on Certain Steel Products from Italy* (58 FR 37327; July 9, 1993); *Results of Remand of Final Negative Countervailing Duty Determination: Certain Fresh Cut Flowers from Mexico,* pursuant to Court Order in *Roses, Inc.* v. *United States,* No. 84–5–00632, Slip. Op. 90–64 (CIT July 3, 1990).

[2] *Final Affirmative Countervailing Duty Determination on Certain Fresh Atlantic Groundfish from Canada* (51 FR 10041; March 24, 1986); *Final Affirmative Countervailing Duty Determination and Partial Countervailing Duty Order on Ball Bearings and Parts Thereof from Thailand* (54 FR 19130; May 3, 1989); and *Final Affirmative Countervailing Duty Determinations on Pure Magnesium and Alloy Magnesium from Canada* (57 FR 30946; July 13, 1992).

Comeau Seafoods vs. *United States,* 724 F Supp. 1407, 1416 (CIT 1989).

Thai Bearings and *Canadian Magnesium* are also similar to the present case. In both cases, a number of different government activities were authorized by a broadly encompassing statute. While the statute outlined the broad goals and parameters of the legislation, the individual component programs were much more specific regarding the eligibility requirements, application procedures, and purposes. As a result, the Department examined each component program under the statute individually. Thus, while the overall goal of FIPA is income stabilization, each component has its own specific purpose (e.g., NTSP—insurance against market price fluctuations, Crop Insurance—insurance against weather related disasters, GRIP—gross revenue insurance, and NISA—whole-farm income loss protection), its own eligibility requirements, its own application and approval procedures, and its own administration.

Thus, the GOC's arguments to the contrary notwithstanding, the Department's decision that FIPA should be treated as several separate programs is consistent with past cases.

Comment 7: The GOC argues that pervasive analytical flaws led the Department to its incorrect preliminary finding that the FIPA options are not integrally linked. First, the GOC argues that the Department confuses FIPA's purpose with risk, delivery mechanisms and benefits. The GOC argues that purpose is the end to be obtained, which in FIPA's case is farm income stabilization. The risks addressed by the FIPA options are the reason for stabilization. If the end is income stabilization, then the means to that end are crop insurance, revenue insurance, and net income stabilization accounts. The Department's assertion that FIPA offers different types of benefits is incorrect. FIPA offers one type of benefit which is income stabilization in the form of financial payments keyed to historical performance. In *Swine VI,* the Department recognized that NTSP, which is a FIPA option, provided for ''only one type of assistance, income stabilization (59 FR 12245).''

Second, the GOC also argues that the Department translates FIPA's policy of equitable treatment into a demand for proof of equal dollar payouts. Because the Department could not find such proof on the record, it concluded that evidence of FIPA's policy to treat commodities equally is inconclusive. This demand for equal dollar payouts misconstrues the meaning of FIPA's equitable treatment. Furthermore, the GOC claims that equal dollar payouts is impossible given the varied nature of the agriculture sector, it would lead to the precise type of inequity that FIPA was designed to avoid, and it would impose a burden of proof that would be impossible for the GOC to meet.

The GOC argues that the Department has interpreted the integral linkage regulation as including an overriding requirement of explicit proof that apparently complementary programs are connected to an overall design, through an express statement in their enabling legislation or other authoritative source. The GOC argues that in applying this factor to FIPA, the Department focused on the ''complementary purpose'' aspect, and compared NTSP with the other programs to ascertain whether basically the same type of assistance is being provided to distinct users. The GOC further argues that the Department's same program/different users paradigm is too limited and that there is no logical or legal reason to limit the complementary aspect of related programs to the user groups, and rule out the paradigm of complementary programs/same users. Collectively, the FIPA components supply what is lacking in each component, and thereby produce the equivalent of a single program coverage. Therefore, argues the GOC, the Department's view of the meaning of a complementary program is more narrow than the term or the regulation warrants.

The GOC also argues that the Department's preliminary analysis of the administration of the programs and the manner of funding inappropriately focuses on the day-to-day operational details of each option rather than their key design features, which is inconsistent with the regulatory considerations. The Department has interpreted the administrative and funding factors as calling for similar, if not exactly identical, programs. As stated in *Swine VI,* the integral linkage regulation ''does not require that the programs be identical.'' *Swine VI* (51 FR 10041, 10046). However, the Department does not account for the fact that at the day-to-day operational level, the administration of the FIPA options will necessarily have differences. These differences are unavoidable in a program that keys benefits to farm income, applies in a country as large and climatically varied as Canada, and integrates certain preexisting administrative structures into a comprehensive new scheme. They are also unavoidable given the different product arrays on Canada's farms and the income risks to which these arrays of production are exposed. Furthermore, the GOC argues that the preliminary notice neither addresses the industry-driven reasons for the differences in some program details nor the Department's past statement that ''differences between the nature and administration of the programs'' will not defeat an integral linkage claim if they ''are necessary because of differences in the nature of the industries being offered benefits * * *'' *Swine VI* (59 FR 12246). In effect, the focus on operational details creates a different and more stringent test than the regulation reasonably permits, and the approach is contrary to basic tenets of administrative law.

Petitioners counter that the GOC's interpretation of the Department's integral linkage analysis ignores the Department's well-established practice, grounded in the legislative history, of interpreting the integral linkage test in a stringent manner. Petitioners further counter that the GOC's arguments are inconsistent with the Department's established interpretation of specificity, integral linkage, and the purpose factor in particular. For example, in *Swine VI,* the Department stated that: ''[p]ermitting respondent governments to loosely connect two or more programs which are otherwise designed to serve different purposes would create just the type of loophole the Department seeks to avoid. Besides being contrary to the Department's specificity practice, doing so would be contrary to Congress' express requirement in the legislative history that the Department should avoid taking an 'overly narrow' or 'overly restrictive' view of its authority to determine specificity . . . This statement implies that Congress intended the Department to view its authority to find specificity broadly and its authority to create exceptions to its normal approach narrowly.''

Petitioners support the Department's finding that the record lacked sufficient evidence demonstrating a policy of equal treatment across all FIPA program options. The GOC's argument fails principally because it ignores the threshold requirement of the integral linkage inquiry, that is, that any allegation of linkage must be supported by objective, documentary evidence. Given this standard, the Department is entitled to demand more than theoretical statements and promises that a program should or might, in practice, result in equal treatment.

Petitioners also counter that the Department is not asking that each FIPA participant receive the same amount of benefits, but rather, is merely requiring that program funding mechanisms and

levels establish similar burdens and offer similar rewards. This is a reasonable demand given the stringent nature of the integral linkage test. It is within the Department's discretion to elaborate on each factor listed in the *Proposed Regulation,* and the integral linkage test was intended to be interpreted stringently.

Finally, petitioners counter that the Department's analysis reflects an understanding that the inevitable differences in the FIPA programs necessarily require different administrative approaches that, in turn, prevent the programs from being identical. Yet even allowing for these differences, the Department has concluded that the distinctions in program funding and administration are sufficiently pronounced to preclude an integral linkage finding. Thus, the Department has adequately balanced the record evidence.

Department's Position: As we stated in the preliminary results, to determine whether these programs are integrally linked we examined the purposes of each program, the administration of each program, evidence of a government policy to treat industries equally, and the funding mechanism of each program. In conducting this analysis, we must determine whether the respondent government has demonstrated ''through objective record evidence that, due to an overall policy or national development plan, it created two or more programs with the express purpose that they complement one another, not only in terms of breadth of availability and coverage, but in similarity of intent, purpose, and administration.'' *Live Swine from Canada; Final Results of Countervailing Duty Administrative Review* (59 FR 12243, 12246; March 16, 1994). Moreover, because the integral linkage policy was created as an exception to our specificity analysis, ''we have interpreted the standard narrowly for granting an affirmative integral linkage determination.'' *Id.* at 12245.

Linkage analysis is conducted on a program-by-program basis, to determine whether two or more programs can be treated as one program for purposes of specificity. The first factor calls for an analysis of the purpose of the programs, as stated in the enabling legislation. The GOC misconstrues the application of this factor because it claims that the stated purpose of FIPA, which is income stabilization, necessarily satisfies this criterion. However, in conducting an integral linkage analysis, the Department's practice is to examine the stated purpose of the alleged complementary programs not the purpose of the umbrella legislation enacted to unify the programs. *See, e.g., Canadian Groundfish* at 10041, 10046. Consistent with this practice, we have analyzed the purpose of each separate program under FIPA.

The purpose of crop insurance and a component of GRIP is to protect the farmer against the risks of weather-related losses. The purpose of the other component of GRIP and NTSP is to protect the farmer against the risk of market price fluctuations. The purpose of NISA is to stabilize the farmer's overall financial performance. These covered risks are prerequisite conditions that trigger the payment. They are essential to the design of each separate program.

The GOC reminds us that in *Swine VI,* the Department recognized that NTSP provided for ''only one type of assistance, income stabilization.'' The GOC asserts that FIPA also offers one unique type of benefit—income stabilization. As a result, the GOC states that FIPA and NTSP offer the same type of benefit.

We disagree with the GOC. First, as discussed in the *FIPA Memorandum,* FIPA does not directly provide benefits. The benefits are provided at the level of NTSP and the other component programs under FIPA. Second, the Department has never determined that FIPA and NTSP have the same purpose. In *Swine VI* we accepted ''income stabilization'' as the purpose of NTSP because in that review we were examining the specificity of NTSP as a single program. In that context, a critical examination of the purpose of the program was not necessary. In this review, we reexamined the purpose of NTSP in the context of linkage analysis. In this analysis, the purpose of the program is a key factor in determining whether two or more programs should be considered as one. Therefore, the Department scrutinized this factor more thoroughly and found that the purpose of NTSP is not income stabilization: the purpose of NTSP is to protect the farmer from the risk of market price fluctuations.

We disagree with the GOC's contention that the Department should assess the complementary nature of programs under a ''complementary programs/same user'' paradigm. If the purpose of the analysis was to assess whether all of the farmer's needs were covered under several programs, then a ''complementary programs/same user'' paradigm would be appropriate. However, the purpose of the specificity test is to determine how widely used are the benefits of a certain program. Thus, the purpose of an integral linkage analysis is to determine whether two or more programs providing the same type of benefit to different users can be considered as one program in order to conduct a specificity analysis. If the same type of benefit is being bestowed, the users of the programs would have to be different. Therefore, for purposes of the specificity analysis, we find that the paradigm of ''same benefit/different users'' is appropriate in establishing whether two separate programs should be considered as one for determining specificity. If the purpose of the analysis was to assess whether all the farmers' needs were covered under several programs, then we would probably use the paradigm put forth by the GOC, i.e., ''complementary programs/same user.'' However, that is not the nature of the inquiry we are conducting here. For example, technology development programs might include offering loans, grants and tax credits to companies purchasing technology. These programs would complement each other because they have the same general purpose and the same users, but a different type of benefit would be provided, therefore, the Department would usually analyze each program separately. Therefore, for purposes of linkage analysis, we are continuing to look for similar programs with different users. *See, e.g., Zenith Radio Corp.* v. *United States,* 437 U.S. 443, 450–51 (1978) (deference should be accorded to the Department's reasonable interpretations of the countervailing duty statute).

The second factor calls for ''evidence of a government policy to treat industries equally.'' Under this factor the Department examines objective, documentary evidence of the existence of such policy. We determined that there was insufficient evidence on the record to ascertain whether such a policy exists. Far from requiring a ''proof of equal dollar pay-outs'', the Department in this case examined the GOC's policy statements contained in the FIPA legislation and in the Parliamentary debates. We also examined the record for any data supporting those policy statements. Such data could have been, for instance, a preliminary study comparing different levels of premiums with different level of benefits for the various programs, used by the drafters of the legislation, or, alternatively, data showing how the GOC actually evaluated ''equal treatment'' based on experience under the new programs. The GOC could not provide such data. Absent such data, the Parliamentary debates and the FIPA legislation cited by the GOC fail to demonstrate a government policy of

equal treatment. As noted in *Swine VI* at 12246, the supporting evidence must go beyond simply identifying a broad underlying goal encompassing several otherwise distinct programs which provide access to benefits to all or most eligible industries. In the seventh period of review, our conclusion was that ''while we recognize that the Parliamentary Debates language reflects an intent to treat commodities equally, we have no evidence that such a policy has been implemented.''

We disagree with the GOC that in analyzing the third factor, the administration of the programs, and the fourth factor, the manner of funding, the Department wrongly focuses on day-to-day operational details of each program rather than their key design features. In analyzing the administration, we examine whether the administration of the programs is consistent with a structure that would allow for the same type of benefits to be provided to different users. In analyzing the manner of funding, we examine whether the levels of funding and the frequency of funding would allow for the same type of assistance to be provided to different users in a consistent manner.

We find that although there are some common features in the administration, and funding is provided by the same three sources, the federal and provincial governments and the producers, there are fundamental differences in the administration and funding mechanisms. These differences are due to the diversity of the programs. Each program is funded for a specific type of assistance but, more importantly, each participant contributes different percentages.

Comment 8: Petitioners argue that in all three reviews the Department should calculate the benefit from the SHARP program based on the full outstanding balance in the SHARP fund plus accrued interest. According to petitioners, the SHARP deficit accumulated over the life of the program due to the chronic imbalance between contributions and payouts. Although loans from the Government of Saskatchewan (GOS) to finance the deficit were in theory to have been repaid, petitioners claim that the size of the deficit makes it likely that deficits existed every year, that the provincial government lent money to the program every year, and that no repayment was ever made. Thus, petitioners argue, the remaining deficit (i.e. the total fund deficit minus the amount of the deficit countervailed in the various reviews) constitutes a subsidy that has not been countervailed.

Petitioners further argue that the outstanding principal (deficit) should be adjusted upwards to account for interest accrued since October 31, 1989. In doing so, petitioners take issue with the Department's statement in the preliminary results that ''when the balance in the SHARP account was insufficient to cover payments to producers, the provincial government provided financing on commercial terms.'' On the contrary, petitioners point out, the SHARP annual report states that no interest was charged on these loans subsequent to October 31, 1989. Therefore, the Department should add accrued interest to the outstanding principal amount.

The CPC counters that the same argument was made by petitioners and rejected by the Department in the sixth review, and therefore should also be rejected in these reviews, given that petitioners have presented no new evidence on this topic. As a result, the Department should continue to base its calculation of the SHARP benefit on one-half of the outstanding deficit during the seventh and eighth reviews. According to the CPC, the ninth review, during which a final decision was made on the disposition of the deficit, is the first appropriate point for an examination by the Department as to whether the loan forgiveness constitutes a countervailable subsidy. With respect to this issue, the CPC argues that the deficit represents payments already made to hog producers and already countervailed.

Department's Position: We disagree with petitioners that the full amount of the SHARP deficit should be countervailed in these reviews. The deficit is a result of loans provided to SHARP by the provincial government to cover payouts when the fund balance was at zero. As such, the deficit amount represents payments already made to producers. We have previously countervailed one-half of all SHARP payouts during prior reviews of live swine. *See e.g., Swine VI,* at 12260. Thus, to the extent that one-half of the payment amount (i.e., the amount attributed to provincial government contributions) was countervailable under the Department's methodology, the Department has in fact already countervailed one-half of the deficit in previous reviews, when the payments to the producers were made. To calculate the benefit in these reviews based on the entire amount of the deficit, as petitioners have suggested, would be to countervail twice the amount of provincial government contributions. The CPC's argument not to countervail any of the deficit amount is equally flawed. The CPC recognizes, based on its own figures, that the Department has countervailed only half of the previous payments made to hog producers that the deficit represents. Therefore, our decision to calculate the benefit to swine producers based on one-half of the deficit amount remains unchanged whether the benefit is represented by the accumulated interest on the unpaid deficit (seventh and eighth reviews) or by the forgiveness of the outstanding deficit amount (ninth review).

Furthermore, we disagree with petitioners that interest accrued since 1989 should be added to the outstanding principal amount (i.e., the deficit) to derive the full amount treated as a grant in the ninth review. In previous reviews, the Department relied on the GOS's statement that ''financing was provided on commercial terms.'' During the sixth review, when it became clear that interest on the loans to the SHARP fund stopped accruing in 1989, the Department countervailed this interest benefit. *Swine VI* at 54118. However, when the Department first examined the SHARP deficit in the sixth review, the disposition of the principal remained uncertain, thus allowing for the possibility that the loans would be repaid (*See* March 2, 1994 Memorandum for Barbara E. Tillman from team regarding *Calculation Methodology for SHARP*, on file in the public file of the CRU). For this reason, we determined that conducting a benefit analysis of the deficit was unwarranted. *Swine VI* at 12260. Therefore, the Department determined that the most appropriate methodology to account for the interest benefit was to treat the deficit as a non-interest bearing short-term loan and to expense the benefit during the review period. *Swine VI* at 12260. We followed this methodology in the seventh and eighth review periods because there had still been no final decision on how to deal with the deficit. Adding accrued interest since 1989 to the outstanding principal amount treated as a grant in the ninth review, other than the interest which accrued during the ninth review period before the deficit was written off, would be inconsistent with the methodology followed in Swine VI and would countervail twice the interest benefit for the period covered by the sixth, seventh, and eighth reviews. Therefore, we determine that accrued interest since 1989 should not be added to the outstanding deficit amount to calculate the amount of the grant bestowed in the ninth review. However, we have added to the written off deficit, treated as a grant in the ninth review, the amount of

interest accrued from the beginning of that review period until the date on which the deficit was written off. (*See also, Department's Position* on *Comment 10*).

Comment 9: Petitioners argue that the Department should use a medium-term interest rate to calculate the SHARP benefits for the seventh and eighth review periods. According to petitioners, the Department's choice of a short-term rate, normally defined as a rate for a loan with a maturity of one year or less, is unsupported by the record. To the contrary, state petitioners, evidence on the record in the seventh and eighth reviews regarding the uncertainty of the treatment of the SHARP deficit more readily supports the use of a medium-term benchmark for calculating the respective interest benefits, as it reflects more accurately that a range of possible outcomes existed.

The CPC argues that the Department's selection of a benchmark interest rate is consistent with the methodology followed in the sixth review. Not until the ninth review was a final decision made on the deficit. The CPC asserts that no new information was available to the Department in the seventh and eighth reviews, and that nothing on the record supports petitioners' suggestion that a medium-term rate would be more accurate than the short-term rate the Department has chosen.

Department's Position: We agree with the CPC. To calculate the benefit to hog producers from the outstanding balance of the deficit, the Department has treated the deficit as a short-term loan *Swine VI* at 12260. As we stated in the *Department's Position* on *Comment 8,* it is appropriate to use our short-term loan methodology for this purpose because the possibility existed, from one review period to another, that the GOS would make a final decision on the disposition of the deficit. Indeed, petitioners correctly point out that there is no information on the record in the seventh or eighth review indicating what would happen to the deficit during the next review period. Therefore, we determine that a short-term rate is still the most appropriate benchmark to calculate the interest benefit on the deficit.

Comment 10: Petitioners argue that, if the Department continues to use a short-term benchmark to calculate the SHARP benefit, it should use rates published by the International Monetary Fund (IMF), rather than by the Organization for Economic Cooperation and Development (OECD), as OECD rates underestimate the benefit provided to swine producers. Petitioners point out that IMF short-term lending rates ''that chartered banks charge on large business loans to their most credit-worthy customers,'' presumably the most attractive rates available, are consistently higher than the OECD rates used by the Department. Therefore, according to petitioners, use of OECD rates is inconsistent with the Department's expressed preference for relying on ''typical'' or commercially available rates.

The CPC points out that the Department has previously used OECD rates (in the sixth review), which are provided to the OECD by the GOC and are based on Bank of Canada statistics. Therefore, the CPC concludes that petitioners' argument is without merit.

Department's Position: We have reexamined the OECD-published interest rates for Canada used in our preliminary results and determined that they are not appropriate to use as benchmark rates for purposes of our calculations. Though provided by the Bank of Canada, as the CPC correctly points out, the OECD rates that the Department used represent chartered banks' interest rates payable on 90-day deposit receipts. As such, they are not appropriate to use as benchmarks for commercial loans. Petitioners are, therefore, correct in their assertion that the lending rates published by the IMF are more appropriate than the OECD deposit rates. Therefore, in the seventh, eighth, and ninth review periods, we have modified our calculations, using short term lending rates published by the IMF rather than the 90-day deposit receipts rate published by OECD.

Comment 11: Petitioners claim the Department has underestimated the benefit to hog producers resulting from the write-off of the SHARP deficit at the end of the ninth review period. According to petitioners, because the loans were forgiven on the last day of the review period, the Department's treatment of the loan forgiveness as a non-recurring grant, allocated over three years, does not account for the additional benefit in the form of interest not accruing on the outstanding loan balance. Petitioners argue the Department should modify its calculations to reflect this additional benefit.

Department's Position: Section 355.44 (k) of the *Proposed Regulations* states that the forgiveness by a government of an outstanding debt obligation confers a countervailable benefit equal to the outstanding principal and accrued unpaid interest at the time of the forgiveness. Because the deficit represents, in effect, an interest free loan, it is appropriate to include as part of the derived grant value, the amount of interest accrued at the time when the deficit was written off. Such an approach is consistent with our methodology in the seventh and eighth reviews, in which we calculated as the benefit the amount of interest which should have been paid. Accordingly, we have modified our calculations for the ninth review period and are adding to the deficit the amount of interest accrued during the review period up to the date on which the SHARP deficit was written off. Consistent with our prior practice in this case, and as explained in the *Department's Position* on *Comment 8,* we are treating one-half of the deficit amount as a non-recurring grant. We have allocated the total grant amount (i.e., one-half of the deficit amount, which equals the provincial government's contribution, plus the accrued interest) over three years, the average useful life of assets in the live swine industry.

Comment 12: Petitioners disagree with the Department's source of feed and grain consumption information used to calculate the benefit from the ACBOP program. According to petitioners, the Department had available on the record in the seventh review the C.R.D. study, a recent comprehensive source of feed and grain consumption information published by Alberta Agriculture. This document, assert petitioners, provides a better reflection of feeding practices of hog producers in Alberta than the unpublished survey relied upon by the Department, which presumably represented more accurate information than that used in prior reviews. The Department should therefore use data from the C.R.D. study, which would allow it to calculate more accurately complete swine diets, including the significant quantity of grain consumed by sows and boars.

The CPC argues that the Department appropriately used specific and detailed data on hog grain consumption that was verified extensively. According to the CPC, petitioners have ignored this detailed and well-documented record and have instead recycled an argument that the Department rejected in the sixth review. The CPC maintains that petitioners' preferred source, the C.R.D. study, does not contain all of the information necessary for the calculations. The purpose of such studies, argues the CPC, is to provide producers with data on possible alternatives to standard practices. Accordingly, the Department should continue to employ the ACBOP calculation methodology used in the preliminary results.

Department's Position: The Department has analyzed the C.R.D. study referred to by petitioners and determined that it is not as comprehensive as petitioners assert. The study does not include information about the composition of ''starter'' diets, which is necessary to the ACBOP calculation. By contrast, the information relied upon by the Department, taken from the Jaikaran study of hog diets and feed consumption, contains data on feed consumed during both the ''creep'' and ''starter'' phases, as well as during the later stages of hog growth. Indeed, the Department examined the summary of the results of the Jaikaran study at verification and found that the document reflects the feed consumed, pigs' weight gain, percentage of grain in the feed, and feed-to-grain ratios for each stage of growth. *See Verification Report* at 32. Thus, the study used by the Department represents the most complete available source of information necessary for the ACBOP calculation methodology. The Department's reliance on the Jaikaran study as the source of feed and grain consumption information therefore remains unchanged.

Comment 13: Petitioners argue that the Department's preliminary determination to classify the New Brunswick Hog Price Stabilization program as ''terminated'' is inconsistent with its decision to monitor the program until 1999 using a ten-year allocation period as stated in the Memorandum from The Live Swine Team to Barbara E. Tillman regarding *Termination of New Brunswick Hog Price Stabilization Program*, May 15, 1996 (*Stabilization Plan Memo*). However, petitioners agree that three years reflects the useful life of the assets in the hog industry and that this period is the appropriate measure for allocating grants in these reviews. To the extent the Department relies on the three-year allocation period, its arguments do not apply.

Department's Position: We acknowledge the discrepancy between the *Stabilization Plan Memo* and the Department's position in the preliminary results. According to the Internal Revenue Service tables, the average useful life of the assets in the hog industry is three years; therefore, the correct allocation period is three years rather than a ten-year period as indicated in the *Stabilization Plan Memo*. Because the program was terminated on March 31, 1989, the last year in which benefits could have been used by swine producers was 1991–92. However, New Brunswick did not export to the United States during that period. Therefore, as stated in our preliminary notice, we consider this program to be terminated, and will not continue to monitor this program.

Comment 14: Petitioners argue that the Department should reclassify the Prince Edward Island Pro Pork Assistance Program (Pro Pork Program) and the Cash Flow Enhancement Program (CFEP) from ''programs preliminarily found not to confer subsidies'' to ''programs not benefitting the subject merchandise.'' According to the petitioners, the Pro Pork Assistance Program is *de jure* specific to hog producers, and hence, countervailable as a matter of law. The program is similar to the Ontario Pork Industry Improvement Program, which the Department has countervailed in previous *Live Swine* reviews. (*Swine VI* at 54120). However, to the extent the Department continues to view the program's alleged emphasis on slaughter hogs as a reason for not countervailing Pro Pork benefits in the seventh period of review, it should, at a minimum, recognize that its decision is only factual, and conclude merely that the program does not benefit the subject merchandise. This classification of the Pro Pork program in this manner will allow the Department to countervail the program in the future in the event that it finds that benefits are available to live swine.

Likewise, petitioners argue that the Department improperly determined that the CFEP advances do not provide countervailable benefits to hog producers because the advances are tied to products other than the subject merchandise. Petitioners contend that finding that benefits are not tied to the subject merchandise is different from finding that benefits are not countervailable *per se*. Indeed, the Department did not engage in a definitive specificity analysis to determine whether CFEP benefits could be countervailed. Under these circumstances, the Department should not have classified CFEP advances with programs for which it had expressly made a non-countervailability finding.

The CPC rebuts petitioner's comments stating that the Department is only required to determine whether or not subsidies are received by producers of the subject merchandise. Once the Department has determined that a program does not benefit the subject merchandise, its practice is to conclude that the program is found not to confer subsidies.

Department's Position: We disagree with petitioners with respect to our classification of both programs. We determined that the Pro Pork Program requires producers to have their entire swine production slaughtered in Prince Edward Island or New Brunswick and payments are made only on dressed pork after slaughter. Therefore, live swine exported to the United States are not eligible for and cannot receive assistance under this program. The Pro Pork Program is distinguishable from the Ontario Pork Industry Improvement Program; this program provided grants to Ontario live swine producers to enable them to improve their productivity, profitability, and competitive position. As such, live swine exported to the United States were not precluded from receiving assistance under the program. Regarding the CFEP, cash advances are limited by the statute to farmers who produce crops for sale and not for consumption on the farm. Therefore, a farmer that uses crops to raise hogs cannot qualify for or receive cash advances under this program. Accordingly, we determined that CFEP did not provide a countervailable subsidy to the subject merchandise. Thus, in accordance with our practice, we determine that neither program confers countervailable subsidies on the subject merchandise.

Comment 15: Petitioners argue that the Department has underestimated the benefits received under FISI. According to the petitioners, the Department's preliminary calculations fail to recognize that payments to swine producers under FISI are not limited to so-called ''compensations,'' but also include advances; both forms of FISI payments provide the same overall type of benefit to Quebec hog farmers. The Department should modify its FISI calculation methodology to include both compensation payments and advances made to hog producers during the period of review. Further, the petitioners argue that the Department should countervail FISI payments on a cash basis rather than on an accrual basis.

According to the GOQ, adding advances to compensation payments would lead to double-counting, because advances are already accounted for in the total compensation figures used in the calculations. The GOQ states that the Department verified that the figures used in the seventh review calculations include compensation and advance payments to hog and piglet producers during the period of review. The GOQ further states that the figures used in the eighth and ninth reviews as FISI payouts in the calculations also account for advance FISI payments to hog and piglet producers.

With respect to whether the Department countervails FISI payments on a cash basis or on an accrual basis,

the GOQ counters that the Department has in fact used in its calculations FISI payment figures recorded on a cash basis. Therefore, the Department does not need to make any changes to the calculations of the alleged FISI benefits to producers.

Department's Position: We disagree with the petitioners. At verification in the seventh review, we noted that advance FISI payments are accounted for in the total compensation figures. (See Countervailing Duty Order on *Live Swine from Canada:* Verification Report (Public Version) dated June 8, 1994, on file in the Central Records Unit, Room B–099, of the Main Commerce Building (Verification Report) at 47–48.) Similar figures were submitted in the eighth period of review. Further, information submitted in the questionnaire responses for the eighth and ninth reviews, indicates that to calculate the amount to be paid out to producers covered under FISI at the end of the period, the Regie subtracts FISI advances from total compensation. FISI advances do not increase the total compensation amount. (*See* February 28, 1994 Questionnaire Response at page III–10, 11; February 27, 1995 Questionnaire Response at VI–700.) Therefore, the Department has appropriately accounted for advance FISI payments to swine producers in the seventh, eighth and ninth reviews in its calculations.

With respect to the petitioners' claim that the Department should countervail FISI payments on a cash rather than accrual basis, it is the Department's normal practice to calculate FISI benefits using figures recorded on a cash basis. In the seventh review, the Department verified the cash-based figures reported in the questionnaire response. The discussion at verification regarding cash versus accrual was only for the purpose of reconciling data submitted in the questionnaire responses to the Regie's financial statements which are maintained on an accrual basis. (See Verification Report at 47.) In the seventh review calculations, we used FISI payment figures on a cash basis as provided in the questionnaire response. In the eighth and ninth reviews, we were consistent and have used the cash basis figures as provided in the record of those reviews. Therefore, the Department has appropriately calculated the FISI benefits using figures reported on a cash basis of accounting.

Comment 16: The petitioners argue that the Department has underestimated the benefits from the FISI program because it failed to address the accumulated deficit in the FISI account. According to the petitioners, because payments to producers have exceeded ordinary FISI scheme funds, the swine funds have incurred deficits financed by the GOQ. Therefore, the petitioners state that the GOQ's funds have accounted for well over two-thirds of the program funding, and the producer funds for well under one-third of total payouts. The petitioners argue that in order to derive the most accurate FISI benefit calculation, it is essential that the Department not impute more than the amount actually contributed by producers during the instant reviews or any future review periods to the producer contributions. The petitioners further argue that because the Department has consistently assumed that one-third of all FISI payments to producers have come from producer contributions, the deficit which has been financed entirely by the GOQ, has only been partially countervailed in past reviews. Thus, the petitioners urge the Department to countervail as an additional amount of FISI benefits the remaining portion of the deficit that has not been countervailed in any previous reviews.

The GOQ states that it is the Department's well-established practice not to investigate deficits in stabilization insurance plans unless and until those deficits are forgiven or interest ceases to accrue. According to the GOQ, the deficits to the hog and piglet FISI accounts have not been forgiven, and there is no indication in the records of the instant reviews that the deficits would be forgiven. Further, the GOQ states that the FISI accounts in deficit continue to accrue interest.

Department Position: We disagree with the petitioners. The Department's practice is to countervail a benefit only when it affects the recipient's cash flow. Section 355.48(a) of the Department's *Proposed Regulations* specifically states that ''the cash flow and economic effect of a benefit normally occurs when a firm experiences a difference in cash flows, either in payments it receives or the outlays it makes, as a result of its receipt of the benefit.'' *See also Final Affirmative Countervailing Duty Determination: Grain Oriented Electrical Steel from Italy,* (59 FR 18357, April 18, 1994), and *Final Results of Reviews: Industrial Phosphoric Acid from Israel,* (56 FR 50854; October 9, 1991).

The existence of a deficit in the FISI account balance does not necessarily constitute a countervailable benefit to the producers. For instance, when the Department found in the sixth review of this order that the SHARP program terminated with a deficit and that interest on the loans resulting in the deficit had stopped accruing, the Department found that the only benefit to the producers at that time was accounted for by the non-accrual of interest on the outstanding balance. *See Swine VI* at 26884.

In these reviews, there is no evidence that demonstrates any cash flow impact on the producers as a result of the deficit. The amount of pay-outs received is not affected by the deficit. As indicated in several record documents (*see,* e.g., the complementary notes to the Regie's Financial Statements, February 27, 1994 questionnaire response at VI–692) and discussed in the preliminary results of these reviews, whenever the balance in the FISI account is insufficient to make payments, the GOQ lends the needed funds to the Regie. These advances are subject to repayment by the Regie and accrue interest (*see,* e.g., line item ''interest on loan'' in the income statements of the FISI fund in the ninth review questionnaire response, February 27, 1994 at VI–689). These loans are properly recorded on the books of the Regie, because they represent a liability of the Regie. The record of each review shows that premiums paid by producers are not reduced by these loans. Premiums are adjusted each year to account for the debt burden, including financing expenses, under each FISI scheme. These adjustments permit the Regie to finance any debt and its related financing expense one-third through producer assessments, and two-thirds through provincial contributions. Thus, unlike the deficit in the SHARP program, the FISI account deficit has not been written-off and interest has not stopped accruing. Accordingly, we have not taken into consideration the deficit in the FISI account in calculating the benefit to swine producers in these three periods of review.

Comment 17: The GOQ argues that the Department cannot rely upon its decision in the sixth review to determine that FISI is countervailable in these reviews (seventh, eighth, and ninth). The GOQ argues that the Department's sixth review results do not establish administrative practice because the sixth review results are in direct conflict with the administrative practice established in Final Affirmative Countervailing Duty Determination; *Fresh, Chilled and Frozen Pork from Canada,* 54 FR 30774, 30779 (July 20, 1989) and the fourth and fifth reviews of *Live Swine.* In those proceedings the Department found in remand determinations that FISI is not countervailable. One determination that is in direct conflict with three other

prior determinations cannot, by itself, establish an administrative practice.

The GOQ further argues that the Department's reasoning with respect to FISI in the sixth review is based upon an irrational methodology that is contrary to the record in these reviews. The finding that FISI was specific in the sixth review was based entirely on the Department's determination that Quebec's agricultural universe consisted of more than 80 products. The mere counting of commodities is an irrational and improper method for determining specificity and the methodology that the Department used to derive the 80 commodities was completely arbitrary. They also argue that any rational analysis of the evidence on the record of the seventh, eighth and ninth reviews would indicate an agricultural universe that is substantially smaller than ''more than 80 commodities'' in Quebec.

Finally, the GOQ claims that in the eighth and ninth reviews, Quebec issued explicit guidelines with respect to creating FISI schemes for new products that removes any discretion from the Regie that might have existed and that may have led to the Department's conclusion that FISI is specific and, therefore, countervailable.

Department's Position: The Department determined in *Swine VI* that the FISI program was countervailable and that decision was not challenged by any party to that proceeding. It is well-established that where the Department has determined that a program is (or is not) countervailable, it is the Department's policy not to reexamine the issue of that program's countervailability in subsequent reviews unless new information or evidence of changed circumstances is submitted which warrants reconsideration. *See, e.g., Industrial Phosphoric Acid from Israel; Final Results of Countervailing Duty Administrative Reviews,* 61 FR 28841 (June 6, 1996), and *Industrial Phosphoric Acid from Israel; Preliminary Results of Countervailing Duty Administrative Reviews,* 61 FR 8255 (March 4, 1996). The United States Court of International Trade (CIT) upheld this practice in *PPG Industries, Inc.* v. *United States,* 746 F. Supp. 119 (CIT 1990) (*PPG Industries*). In *PPG Industries,* the court ruled that ''Commerce has discretion in deciding whether to investigate a program previously found not countervailable (or countervailable) in a final agency determination; in reaching its decision Commerce is entitled to draw upon its own knowledge and expertise and facts capable of judicial notice.'' *Id.* at 135.

The GOQ is aware of the Department's policy not to reexamine the countervailability of a program absent new information or changed circumstances. The Department has clearly communicated the application of this policy throughout the seventh, eighth, and ninth reviews, in which the Department's questionnaires stated clearly that, ''absent new information or evidence of changed circumstances, we do not intend to examine the countervailability of programs previously found to be countervailable.'' This standard language, which reflects the Department's practice, is included in every questionnaire used in CVD administrative reviews.

The GOQ's claim that the Department's decision on FISI in the sixth review is in conflict with the administrative practice established in the remand determinations in *Fresh, Chilled and Frozen Pork from Canada* and the fourth and fifth reviews of *Live Swine* is misplaced. In those determinations upon remand, the Department complied with panel decisions that requested the Department to reconsider certain aspects of the underlying methodology used in those determinations, respectively. The panel's decisions are binding only on the proceeding which is under panel review and therefore are not of precedential value. None of those remand determinations established any overriding policy which was adaptable to other reviews based upon different administrative records.

In the instant reviews, the GOQ has presented no new evidence on the record which would warrant reconsideration of the Department's determination in *Swine VI* that FISI is countervailable. Because there is no new information or evidence of changed circumstances, the Department has not reexamined the countervailability of the FISI program. To do so would be inconsistent with the Department's long-standing practice, which has been duly articulated in these reviews.

The GOQ's argument that specific guidelines issued by Quebec removed any discretion from the Regie that might have existed with respect to conferring FISI benefits is insufficient to reopen our inquiry. As discussed in detail in *Swine VI,* we did not base our determination that FISI is *de facto* specific on evidence that the GOQ exercised discretion in determining which products receive schemes. *Swine VI* at 12254. Rather, our determination, reached after an examination of all factors, was based upon the small number of actual users in relation to the universe of eligible beneficiaries. This finding alone warranted an affirmative determination of *de facto* specificity (*Swine VI* at 12252), and there has been no increase in the actual number of users of FISI. Therefore, a change in the amount of discretion exercised by the GOQ does not constitute new information sufficient to warrant reexamination of our determination.

The GOQ has also made arguments that the Department's decision in *Swine VI* was in error. While there are fora in which the GOQ could have made such challenges, as noted above, the parties to that proceeding did not avail themselves of that opportunity.

Comment 18: The GOQ disagrees with the Department's preliminary determination that FISI, crop insurance and supply management are not integrally linked. Citing the *Proposed Regulations* at section 355.43(b)(6), the GOQ notes that, because there is no prescription in the regulations as to what the answers to each integral linkage criterion ought to be, the Department should find programs to be integrally linked if it determines that two or more programs are intended to accomplish the same ultimate end and, in doing so, treat industries equally, even if the means to accomplish those ends are somewhat different. According to the GOQ, a requirement that the means also be the same as the end would make the integral linkage provision meaningless, because, in effect, such a requirement would mean that the programs must be identical. The GOQ notes that this is in direct conflict with explicit statements made by the Department that programs need not be identical to be integrally linked. Such a requirement would also directly conflict with the rationale for the integral linkage regulation, which the GOQ states is to avoid finding programs that benefit a broad section of the economy countervailable simply because, for political or technical reasons, a government set out to accomplish the same result through two or more complementary but not identical programs. Using this test, the GOQ claims that FISI, crop insurance and supply management are integrally linked because these three programs provide comprehensive insurance against the risks to which Quebec farmers are subject.

According to the GOQ, the Department found in the preliminary results that the administration and manner of funding for FISI and Crop Insurance are similar and that the evidence with respect to equal treatment was inconclusive; the Department reached the conclusion that FISI and Crop Insurance are not linked only because it improperly determined that the purposes of the programs are

different. According to the GOQ, FISI and Crop Insurance serve exactly the same purpose, stabilizing farmers' income, using different methods, namely insuring farmers against the various risks inherent in farming. The GOQ argues that the Department reached the wrong conclusion because it confused method with purpose; the GOQ defines the purpose as the ''common result'' of FISI and Crop Insurance, i.e. income stabilization.

To demonstrate that the two programs are ''complementary parts of an overarching governmental policy directive,'' the GOQ cites to the legislative history of FISI and Crop Insurance, pointing out that the Quebec's legislature explicitly tied FISI and Crop Insurance together as complementary parts of the government's overarching policy of insuring income stability in the agricultural sector. According to the GOQ, FISI and Crop Insurance accomplish this goal through similar methods.

With respect to the other factors involved in linkage analysis, the GOQ points out that the administration of FISI is identical to that of Crop Insurance; that the two programs share the same source of funding, accounting system, and personnel; and that each producer has approximately the same ratio of its income at risk, whether they participate in FISI or Crop Insurance, or both.

The GOQ also states that FISI and Crop Insurance are integrally linked with Supply Management. All three plans share the same purpose (farm income stabilization), similar methodology (per unit price based on cost of production), and treat all farmers equally by insuring that they all receive an income from agriculture that provides them a reasonable rate of return over their cost of production.

Petitioners take issue with the GOQ's broad interpretation of the purpose factor of the integral linkage provision; in the petitioner's view, the GOQ ignores the Department's practice of interpreting the integral linkage provision narrowly in order to prevent subsidizing governments from creating a loophole to insulate otherwise actionable programs. Petitioners also argue that the GOQ understates the significance of the different risks associated with FISI, crop insurance, and supply management, failing to recognize that such risks are central to the purpose of the programs. Furthermore, petitioners find that the GOQ overstates the significance of FISI's legislative history when the GOQ concludes that statements made by Quebec legislators regarding the similarities of FISI and crop insurance render the programs complementary. Petitioners argue that such statements do not constitute the type of documentary evidence contemplated by the Department's regulations. *See Swine VI* at 12,246. With respect to the funding and the administration of these programs, petitioners state that the Department has reasonably weighed the factual evidence relating to these factors and properly concluded that such evidence is insufficient to meet the integral linkage test.

Department's Position: We disagree with the GOQ's argument that we incorrectly analyzed whether FISI, Crop Insurance, and Supply Management are integrally linked. The integral linkage policy constitutes an exception to our specificity analysis. *Swine VI* at 12,246. The *Proposed Regulations* require the Department to ''determine the specificity of a program * * * solely on the basis of the availability and use of the particular program in question.'' The specificity test was designed to avoid carrying the countervailing duty law to absurd results by countervailing government actions or programs such as public highways and bridges which clearly benefit the economy at large. In implementing the appropriate standard to determine whether to permit a particular exception to the program-by-program approach of the specificity test, however, the Department cannot create a loophole which would allow *de facto* specific subsidy programs benefitting only particular segments of the economy—or particular segments of the agricultural sector—to escape the imposition of countervailing duties. ''Permitting respondent governments to loosely connect two or more programs which are otherwise designed to serve different purposes would create just the type of loophole the Department seeks to avoid.'' *Swine VI* at 12,246.

As we stated in the preliminary results, to determine whether these programs are integrally linked, in accordance with the criteria established in section 355.43(b)(6) of the Department's *Proposed Regulations,* we examined the purpose of each program, the administration of each program, the record evidence of a government policy to treat industries equally, and the funding mechanism of each program. *See* Memorandum for Paul J. Joffe from The Team on Farm Income Stabilization Insurance—Integral Linkage, dated May 15, 1996, filed in the public file in the Central Record Unit, Room B–099, Main Commerce Building (*Decision Memorandum*).

With respect to the purpose of the programs, we clearly defined the Department's interpretation of what constitutes the purpose of a program and identified the two steps of our analysis: (1) we began by looking at the purpose of each program as described in the enabling legislation and (2) we then examined FISI, Crop Insurance, and the Supply Management programs to ascertain whether they are complementary programs within the meaning of the test articulated in the sixth review, i.e. whether ''*basically the same type of assistance is being provided to distinct users/commodities* or groups of users/commodities.'' (emphasis added). (*Decision Memorandum,* at 5).

The evidence in the record does show that FISI and Crop Insurance are part of ''an overall government policy or national development plan,'' (see *Carbon Steel Wire Rod from Saudi Arabia; Final Results of Administrative Review and Revocation of Countervailing Duty Order,* 59 FR 58814, 58817). The legislative history of the Farm Income Stabilization Act indicates that the Canadian government intended the programs to serve as a means for achieving a broad goal of income stabilization in the agricultural sector. However, in integral linkage analysis, mere evidence of general legislative intent connecting various programs is not dispositive. In fact, broad legislative goals can be achieved through a wide variety of programs. Therefore, in determining whether programs are ''integrally linked'' such that they should be viewed as a single program for specificity purposes, we also look to see whether a specific purpose, i.e., to provide a certain type of assistance, is shared by several programs which complement each other by reaching different users.

We concluded that there is no similarity of purpose between FISI and Crop Insurance, providing, as they do, protection against different types of risks (one against market-price fluctuations and the other against weather-related disasters). However, there is some similarity in purpose between FISI and the supply management programs in that they both protect a farmer's income against losses due to fluctuations in market price.

With respect to the administration of the programs, we found that there are differences among the programs, which are directly related to the different purposes of the programs themselves. We found that FISI and Crop Insurance operated in similar but not identical ways, as the GOQ states in its brief. Both FISI and Crop Insurance are structured

as insurance programs and are administered by the same agency; the procedures to calculate the amount of compensation are similar, in some instances even correlated. Differences appear to be related to the type of coverage offered by each program. In contrast, Supply Management has a totally different administration system. The Supply Management Programs operate on a national, as well as provincial level, because they require the cooperation of producers in all provinces, and are administered independently of FISI and Crop Insurance.

With regard to the evidence of a government policy to treat industries/commodities equally, we concluded that because of the differences between the programs, often not quantifiable, our analysis of the record evidence yielded inconclusive results. The actuarial study submitted by the GOQ in support of the claim of equal treatment was not sufficiently detailed to support this conclusion because the data contained in that study was finalized only for ''vegetable schemes''. The analysis of the livestock data was only preliminary and did not break out information pertaining to live swine. Therefore, no information on this factor was provided on the subject merchandise. Furthermore, this study does not provide the basis for a meaningful analysis of ''equal treatment'' of the agricultural commodities produced in Quebec under this program for several reasons, among them the fact that it does not provide information about individual commodities. The study is based on an analysis of the amount that the farmer has at risk; this can be one of the factors but not the only factor we examine in this type of analysis. Additionally, the record presents information inconsistent with the results of that study. For instance, the GOQ's share of premium payments was not the same in the two programs and GOQ officials acknowledged at verification that benefits to producers under supply management were greater than those provided by FISI. The GOQ's comment that under FISI and Crop Insurance each producer has approximately the same ratio of its income at risk relies on the same actuarial study and therefore presents the same evidentiary deficiencies.

Finally, with respect to the manner of funding, we found that the three programs use two different funding mechanisms: FISI and Crop Insurance are premium funded, with the government and the producers sharing the costs. Under the federal Supply Management programs, there is no direct provision of government funds: farmers pay for the direct costs of operating the program through levies on the sales of their products.

Based on our detailed analysis, we concluded that although there are some common features among the programs, the differences in the purposes of the programs, manners of funding, and the lack of conclusive evidence of a government policy to treat industries equally warrant a finding that the programs are not integrally linked.

The GOQ's dispute with our determination is based on our analysis of the ''purpose'' element. As indicated above, in examining the purpose, while we look at the overall goals of the enabling legislation, we focus on the specific purposes of the programs alleged to be linked. As we stated in the *Decision Memorandum*, specificity analysis must be focused at the program level. In this context, we must examine the type of assistance provided when analyzing the purpose of the program. Contrary to GOQ's claims, this interpretation does not require identical programs, but it does ensure that our integral linkage analysis comports with the countervailing duty law.

According to the GOQ, in determining that FISI and Crop insurance do not share the same purpose, we are confusing method with purpose. We disagree. We are not confusing method with purpose, we are requiring, however, that given the narrow parameters of this type of analysis, the purpose and the method (i.e., the type of assistance) be the same. This does not mean that the programs need to be identical because the programs bestowing the same type of assistance to different groups of users may still be different in some ways to efficiently service different types of users. In our analysis, for instance, we found that FISI and Supply Management share similar purposes, because both programs protect the farmer against fluctuations in market price . Yet, they are very different programs.

The GOQ offers a different interpretation of the rationale underlying the linkage policy. Rather than ensuring the noncountervailability of *programs that benefit the economy at large*, the GOQ proposes the following rationale: ''to avoid finding programs that benefit a broad section of the economy countervailable simply because, for political or technical reasons, a government set out to accomplish the same result through two or more complementary but not identical programs.'' (GOQ's case brief , July 8, 1996, at 43.) The Department's formulation focuses on whether the multiple programs alleged to be linked may constitute one program. In the GOQ's formulation, the key factor appears to be the accomplishment of certain objectives and whether the programs alleged to be linked, although diverse, accomplish those objectives when grouped together. Clearly, the GOQ's interpretation is inappropriate for purposes of this analysis.

Based on this interpretation of integral linkage analysis, which we do not share, the GOQ articulates a new test: programs are linked ''if two or more programs are intended to accomplish the same ultimate end, and in doing so, treat industries equally, even if the means to accomplish those ends are somewhat different.'' The test the GOQ proposes is inappropriate because it relies on a misinterpretation of the rationale of the integral linkage analysis. If we were to use the ''ultimate end'' as the dispositive factor, together with equal treatment, as the GOQ suggests, we would provide governments with the type of loophole that the Department seeks to avoid. *Swine VI* at 12246. Governments often pursue economic objectives, such as energy conservation policies, using different types of programs. Under the GOQ's proposed test many if not all such programs would be integrally linked and would be analyzed jointly for specificity purposes. This result contradicts the intent of Congress that the Department not adopt an overly broad exception to our specificity analysis. *Swine VI* at 12246.

The GOQ's definition of purpose as ''ultimate end'' is inappropriate for a more fundamental reason as well. The GOQ's definition confuses the purpose of the program with the economic effects of the benefits bestowed by the program. Income stabilization is the economic goal of the Farm Income Stabilization Act, not the purpose of FISI, nor of Crop Insurance, nor of the Supply Management programs. The purpose of FISI and Supply Management on the one side and of Crop Insurance on the other is to protect farmers against two distinct risks, price fluctuations and weather-related disasters; income stabilization is the economic effect of that protection. In evaluating subsidies, the Department does not take into account the results or the economic effects of the subsidy. *See, e.g., Final Affirmative Countervailing Duty Determination: Certain Steel Products from Austria (General Issues Appendix)* 58 FR 37217, 37260 (July 9, 1993).

The ''ultimate end'' is in fact of little consequence in linkage analysis. The question posed is whether the two

programs, considered in isolation, have the same specific purpose and bestow the same type of benefits on different users. If they do, provided that the analysis of their administration and manner of funding does not detract from this determination and that all necessary documentation has been provided, treating them as a single program may be appropriate for purposes of a specificity finding.

Comment 19: The GOQ argues that combining the records of the seventh, eighth, and ninth reviews is contrary to the express rulings of the Court of International Trade (CIT) that the record for each section 751 review is limited to that particular review. The GOQ contends that the Department is required to make its determination of whether a given program is countervailable based upon facts specific to the particular review period. The preliminary results reached conclusions as to countervailability based upon all of the information in the combined records, without any attempt to tie those conclusions to the specific facts pertaining to each review period. Thus, the GOQ concluded that it was deprived of its legal right to receive separate determinations regarding the countervailability of its program based on the record of reach review. Furthermore, the GOQ contends that a reviewing court is required to assume that the Department has considered all information on the record. Because the Department has combined all of the information collected in three review periods into a single record, the Department cannot ask a reviewing court to assume that the Department considered only part of the record before it in making its determination.

The GOQ also argues that the Department's inclusion of substantial unverified information is contrary to the statutory requirement that ''all information relied upon in the determination'' be verified. The Department's statutory obligation to verify all of the information used in every third administrative review can no longer be satisfied once the Department combines the records of the seventh, eighth and ninth review periods. The verification that the Department conducted in the seventh review period would satisfy this statutory requirement only as long as the record of the seventh remains separate from the records of the eight and ninth review periods. Although the Department preliminarily calculated separate rates for each period, it made single determinations applicable to all three review periods as to whether programs were countervailable. Thus, the Department's results for the seventh review must be considered to be based, at least in substantial part, on the unverified information collected in the eighth and ninth reviews.

The GOQ further argues that the combination of the records of three administrative reviews unduly burdens the interested parties' right to judicial review. The GOQ claims that it and other interested parties should not be forced to appeal the results of the seventh, eighth and ninth reviews in order to challenge the results, for example, of the seventh review. Interested parties are entitled to separate determinations that a court can review based solely upon the record compiled for a particular review period.

Finally, the GOQ claims that the Department decided to combine the records of the three reviews in secret, without providing interested parties with notice and an opportunity to comment. The combination of the records, contravening the rulings of the CIT, is not a mere procedural adjustment; it violates the rights of parties and transforms the proceedings.

Petitioners counter the GOQ's arguments stating that the Department has thoroughly explained its reasons for proceeding with these reviews on a consolidated basis. This is all that is required under the law. The fact that the GOQ believes that the Department should have solicited comments from interested parties prior to combining the reviews does not render the Department's decision erroneous. On the contrary, petitioners contend that the Department's decision to consolidate the review streamlines the process, avoids duplication of information that is the same across the review periods, and in turn, makes it easier for the Department to identify and address the differences that are relevant to each period.

Finally, the petitioners contend that even if the Department did not inform the GOQ that it was considering the possibility of consolidating the records, this fact does not preclude the Department from doing so. The law is clear that the agency has the discretion to implement whatever procedures are necessary to perform its statutory mandate.

Department's Position: The GOQ misconstrues the manner in which we have conducted the instant reviews. We are conducting concurrent reviews of three different review periods, and we have based the results of each administrative review solely on information submitted for each such review period. We have relied on public information from a preceding review period where that information is related to a common issue in the review period under examination. The Department did not take into account information filed for a subsequent review period to render its decision in an earlier review period. For instance, a decision made in the eighth review is based on information submitted pertaining to the eighth review period, and, where appropriate, public information pertaining to the seventh review period or earlier review periods. This is consistent with the Department's practice and in no way violated the rule that we must base our determinations on the facts contained in the administrative record for each particular review. While the record is combined, we were very careful in ensuring that only information pertaining to a particular review period was used in making determinations and calculating rates for that review period. We did not rely on the record in the way the GOQ alleges. Therefore, we have not combined the records in the manner that GOQ is arguing. Rather, we combined the records to avoid duplication in the submission of information from parties where the prior review had not been completed, and to publish a single notice with separate results for each review period.

In addition, the GOQ incorrectly argues that because the Department combined a verified review, the seventh review, with the other unverified reviews, the verified information no longer satisfies the statutory requirement. This misinterpretation by GOQ also stems from its misunderstanding of the manner in which the Department combined the records and conducted the reviews.

The GOQ makes a blanket statement that the Department reached conclusions as to countervailability based on the record of all three reviews, without attempting to tie those conclusions to specific facts pertaining to a specific determination. Furthermore, the GOQ does not point to any specific errors the Department made as a result of conducting these reviews concurrently. The GOQ's claim that we failed to reach separate determinations with respect to the countervailability of reviewed programs in each proceeding misinterprets our administrative practice. As we have repeatedly stated and as the GOQ well knows, where the Department has determined that a program is (or is not) countervailable, it is the Department's practice not to reexamine that program's countervailability in subsequent reviews unless new information or evidence of changed circumstances has been submitted which warrants

reconsideration. Therefore, we have not reconsidered previous determinations of countervailability unless warranted by evidence on the record of each review period.

Moreover, interested parties' right to judicial review is not unduly burdened. Section 355.3(a) of the Department's regulations states that ''for purposes of section 516a (b)(2) of the Act, the record is the official record of each judicially reviewable segment of the proceeding.'' The concurrent reviews constitute separate segments of the proceeding for purposes of judicial review, and any or all of the three reviews will be subject to judicial review. The Department has conducted concurrent reviews in other proceedings which have been subject to judicial review and this practice has not unduly burdened appellate review. *See generally, NEC Home Electronics, Ltd.* v. *United States,* Slip Op. 94–70 (CIT May 2, 1994) (judicial review of a final notice that contained determinations for four review periods).

The GOQ's argument that the Department decided to combine the records of the three reviews in secret suggests that the Department is obligated to solicit comments before conducting concurrent reviews. The Department has full discretion to implement procedures that it deems necessary to perform its statutory mandate. *See e.g., PPG Industries, Inc.* v. *United States,* 928 F.2d 1568 (Fed. Cir. 1991) (Commerce ''has been given great discretion in administering the countervailing duty laws.'') The GOQ is well aware that the second and third administrative reviews of this order were conducted concurrently. Furthermore, when the seventh and eighth reviews were being conducted concurrently, the GOQ did not raise any objections. The GOQ does not provide any evidence that concurrently conducting the ninth review with the seventh and eighth reviews corrupts the information submitted in any of the reviews.

Comment 20: The GOQ argues that combining the records would increase the risk of inadvertent disclosure of proprietary information to individuals not entitled to receive that information. The GOQ also argues that the Department incorrectly stated in its Memorandum for the File from the Team regarding the *GOQ's Objection to Combining the Administrative Record for the 7th, 8th, and 9th Reviews of Live Swine from Canada (Objection Memo)* dated May 15, 1996, that the GOQ itself has not submitted any BPI during these three reviews, and thus cannot suffer any injury as a result of the ITA's handling of BPI during the seventh, eighth, and ninth reviews.

Department's Position: The GOQ's argument that combining the administrative reviews will result in unlawful disclosure of proprietary information to parties not subject to an administrative protective order (APO) is without merit. All parties to this proceeding (Counsel for the GOC, Counsel for the GOQ, Counsel to the Petitioner, and Counsel for the CPC) had APO's approval for each of the three reviews, and subsequently requested a single ''blanket'' APO for the consolidated proceeding. All information submitted in the three reviews has been treated appropriately.

Comment 21: GOQ argues that the doctrine of collateral estoppel precludes the Department from finding FISI countervailable because the binational panel found that the Department's decision in the fifth review was not based on substantial evidence and was not in accordance with law. Therefore, GOQ argues that the Department is estopped from claiming that FISI is countervailable in the current reviews.

GOQ claims that the binational panel process replaces judicial review of final antidumping and countervailing duty determinations pursuant to the U.S.-North American Free Trade Agreement (NAFTA Article 1904.1). The NAFTA parties have agreed that a binational panel decision, such as the *Swine V* panel decision, shall be binding on the involved Parties with respect to the particular matter between the Parties that is before the panel. (*In the Matter of Live Swine from Canada,* USA–91–1904–04; June 11, 1993). GOQ further argues that because a binational panel decision is a final ruling that is not subject to appeal to any higher tribunal, the decision should carry even more weight than a CIT decision.

GOQ argues that the four conditions for collateral estoppel have been met: (1) the issue previously adjudicated is identical, (2) the issue was litigated in a prior review, (3) the previous determination of that issue was necessary to the end-decision then made, and (4) the party precluded was fully represented by counsel in the prior action.

Petitioners counter that GOQ's arguments fail primarily because they rest on the incorrect premise that the Department previously has found FISI non-countervailable. Contrary to GOQ's claims, the Department has found FISI to be *de facto* specific and therefore countervailable in the original investigation and all subsequent reviews. *See, e.g., Live Swine and Fresh, Chilled and Frozen Pork from Canada,* (50 FR 25097, 25104; June 17, 1985). Petitioners also counter that the binational panel did not find FISI non-countervailable. Rather, the panel reviewing the *Swine V* redetermination found only that the evidence used by the Department was defective, and for that reason, remanded the Department's finding with instructions for it to remove FISI benefits from its duty calculation for that particular review period.

Petitioners further contend that the GOQ's argument that ''a binational panel decision should carry even more weight than a CIT decision'' directly contradicts Congressional intent with respect to the binational panel review process. According to petitioners, the law is clear that decisions of binational panels carry relatively little weight, and certainly could not supersede the CIT's binding decision upholding that FISI is countervailable. *See Alberta Pork Producers' Marketing Board* v. *United States,* 669 F. Supp. 445, 451–52 (1987).

Finally, petitioners counter that GOQ has offered no new factual information requiring the Department to reexamine its previous finding that FISI is *de facto* specific. Therefore, in this regard, it is GOQ's attempt to re-litigate this well-settled issue without offering new facts to compel a different result.

Department's Position: We disagree with the GOQ's argument that we are collaterally estopped by the panel decision in *Swine V* from relying on our determination in the sixth review that FISI is countervailable. First, as recognized by the *Swine V* panel, its decisions are not binding on subsequent administrative determinations. Panel decisions are binding only on the particular matters presented which are based on the particular administrative record subject to appellate review. *Live Swine from Canada,* 14 ITRD 2388, 2403–04 (1992).

Second, the Courts have recognized that collateral estoppel is inapplicable when the Department's determinations are based on different administrative records. *See PPG Industries* v. *United States,* 746 F. Supp. 119, 133–34 (CIT 1990); *PPG Industries* v. *United States,* 978 F.2d 1232, 1239 (Fed. Cir. 1992). *See also Live Swine from Canada,* at 2403 (rejecting use of collateral estoppel to bind panel to previous panel proceedings). The *Swine V* panel decision was based on the record developed in the fifth administrative review. During the sixth review, the Department gathered additional information and reinvestigated the countervailability of FISI. In *Swine VI,* the Department conducted a complete analysis of whether FISI was specific

and determined, based on the record evidence in that review, that FISI was specific. No parties challenged that determination.

Moreover, the CIT has stated that ''the burden on the party seeking issue preclusion is and should be exacting.'' *PPG,* at 134, citing *PPG Industries Inc.* v. *United States,* 712 F. Supp. 195 (CIT 1989). The GOQ has failed to meet this standard because its arguments are based entirely on a non-binding panel decision that reviewed an entirely different administrative record than the record which served as the basis for our determination that FISI is countervailable. Accordingly, in accordance with our long-standing practice, we have relied on our decision in the sixth review that FISI is countervailable and have not reexamined the program because the GOQ has failed to present new facts or evidence of changed circumstances to warrant a reexamination of the program (see *Department's Position* on *Comment 17*).

Comment 22: The CPC argues that the Department's unexplained and undocumented change in production figures in its calculation methodology is not supported by any record evidence. The CPC states that the Department has always used the total swine production data published in the Supply-Disposition Balance Sheets (Balance Sheets) by Statistics Canada. This data, which was verified in the seventh review period, is calculated using three components of the Balance Sheets: slaughter, international exports, and deaths and condemnations. Therefore, the CPC argues that the Department should not exclude deaths and condemnations, without a reasoned explanation. The CPC states that it is well established that an agency must either conform to prior decisions or explain its reason for departure from its past practice. The CPC cites a recent Binational Panel convened under the North American Free Trade Agreement, which ruled in similar circumstances that ''Commerce must provide * * * a comprehensive and reasoned analysis for reversing its former policy * * * Where no such basis of decision appears, there is present the kind of arbitrary action that this panel, like the United States courts, is charged with curbing.'' *In the Matter of Live Swine from Canada,* Panel No. USA–94–1904–01, at 8 (May 30, 1995 Decision of the Panel).

The CPC argues that the Department should continue to use production figures that include dead and condemned animals because they have been produced and marketed, and the scope of the order does not restrict the subject merchandise to human consumption only. Therefore, if the subject merchandise is produced and marketed in any way, it should be included in the total produced and marketed figure. If benefits are not allocated over total production, then any reduction in the production figures used in the denominator of the duty calculation would have to be accompanied by a concomitant reduction in the benefits used in the numerator to include only benefits to those particular animals actually included in the denominator. The CPC also argues that the Department has consistently allocated NTSP benefits over all Canadian production.

Petitioners counter that the CPC attempts to discredit the Department's methodology on evidentiary grounds by claiming that the Department ''apparently rejected verified data on live swine production, and has instead produced its own, unsupported, production figures for use in all benefit calculations.'' The calculations in these reviews are also based on the data provided by the GOC, which the Department verified.

Petitioners also counter that eliminating dead and condemned hogs from the denominator renders the Department's calculations more consistent with the scope of the order, which covers live swine, and with the Department's normal practice of collecting data on live swine produced and marketed or sold for slaughter. Because condemned swine, like dead swine, are not produced and marketed for human consumption, they should be excluded from the denominator. Furthermore, the Department's approach is more consistent with its ''tying'' standard. Under this standard, whenever possible, the Department attempts to tie the countervailable benefit to the actual product or sale benefitting from the subsidy. Petitioners do not dispute that the approach of tying benefits to the merchandise supports including dead and condemned swine in the denominator for ACBOP and the Ontario Rabies Indemnification Program. However, to use multiple denominators for the large number of countervailable programs would pose an administrative burden on the Department. In that context, petitioners conclude that the use of one consistent denominator makes the most sense.

Finally, petitioners state that the CPC's argument that the amended methodology cannot be used for the final results because it represents a change in the Department's practice is incorrect. According to petitioners, the mere fact that an agency reverses a policy * * * does not indicate the agency's decision is unreasonable, arbitrary or capricious. It is well-settled that such reversals are entitled to deference from the courts.

Department's Position: In the seventh review period, in a letter dated August 30, 1993, petitioners challenged the inclusion of dead and condemned swine in the production data. During verification, the GOC said that ''these animals are not sold as live swine, but they are used for some purpose, i.e., fertilizer or consumed on the farm.'' (Verification Report dated June 8, 1994, pgs. 61, 62.) Additionally, the CPC states that ''deaths refer to losses on a farm after a hog has been weaned and is being finished for slaughter, but before the hog is marketed, and condemned hogs are condemned after slaughter.''

Contrary to the CPC's argument that the Department created its own, unsupported production figures, we used data from the Supply-Disposition Balance Sheets (Balance Sheets), which is a GOC publication that the Department verified (Ibid., p. 61). In the preliminary results, we deducted the number of dead and condemned animals provided in that Balance Sheet from the total production figure, taken from the same Balance Sheet.

The CPC incorrectly argues that the Department has consistently allocated NTSP benefits over all Canadian production. On the contrary, the Department has consistently allocated NTSP benefits over the production of market hogs only, because only market hogs are eligible to receive NTSP benefits. See, *Live Swine from Canada; Preliminary Results of Countervailing Duty Administrative Review* (58 FR 54112, 54117; October 20, 1993 and *Swine VI* (12243).

However, after considering the CPC and petitioners' comments, we have determined that we will continue to exclude dead and condemned swine from the denominator in calculating NTSP, FISI and SHARP benefits because these programs are tied to live swine that meet certain criteria of size and eligibility. Dead and condemned hogs are not eligible for benefits under those programs. We have now modified the calculations for the other domestic subsidy programs to include dead and condemned swine in the denominator because these programs are provided to all swine, whether marketed as live swine, or dead or consumed on the farm. This approach is more consistent with the Department's practice of tying benefits to the production or sale of a

particular product(s), in accordance with 19 CFR 355.47(a) of the *Proposed Regulations.*

Final Results of Reviews

For the period April 1, 1991 through March 31, 1992, we determine the total net subsidy on live swine from Canada to be Can$0.0601 per kilogram. For the period April 1, 1992 through March 31, 1993, we determine the total net subsidy on live swine from Canada to be Can$0.0613 per kilogram. For the period April 1, 1993 through March 31, 1994, we determine the total net subsidy on live swine from Canada to be Can$0.0106 per kilogram.

The Department will instruct the U.S. Customs Service to assess countervailing duties of Can$0.0601 per kilogram on shipments of live swine from Canada exported on or after April 1, 1991 and on or before March 31, 1992, Can$0.0613 per kilogram on shipments of live swine from Canada exported on or after April 1, 1992 and on or before March 31, 1993, and Can$0.0106 per kilogram on shipments of live swine from Canada exported on or after April 1, 1993 and on or before March 31, 1994.

The Department will also instruct the U.S. Customs Service to collect a cash deposit of estimated countervailing duties of Can$0.0106 per kilogram on shipments of all live swine from Canada entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice.

This notice serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 355.34(d). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

These administrative reviews and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR 355.22.

Dated: September 25, 1996.

Robert S. LaRussa,

Acting Assistant Secretary for Import Administration.

[FR Doc. 96–25648 Filed 10–4–96; 8:45 am]

BILLING CODE 3510–DS–P

[C–122–404]

Live Swine From Canada; Preliminary Results of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of preliminary results of countervailing duty administrative review.

SUMMARY: The Department of Commerce (''the Department'') is conducting an administrative review of the countervailing duty order on live swine from Canada. For information on the net subsidy for all producers covered by this order, see the *Preliminary Results of Review* section of this notice. If the final results remain the same as these preliminary results of administrative review, we will instruct the U.S. Customs Service to assess countervailing duties as detailed in the *Preliminary Results of Review* section of this notice. Interested parties are invited to comment on these preliminary results.

EFFECTIVE DATE: October 7, 1996.

FOR FURTHER INFORMATION CONTACT: Stephanie Moore, Cameron Cardozo, Brian Albright or Norma Curtis, Office of Countervailing Duty/Antidumping Enforcement VI, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–2849 or (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Background

On August 15, 1985, the Department published in the Federal Register (50 FR 32880) the countervailing duty order on live swine from Canada. On August 1, 1995, the Department published a notice of ''Opportunity to Request Administrative Review'' (60 FR 39150) of this countervailing duty order. We received timely requests for review and we initiated the review, covering the period April 1, 1994 through March 31, 1995, on September 15, 1995 (60 FR 47930).

As explained in the notice of initiation, the Department has determined that it is not practicable to conduct a company-specific review of this order because a large number of producers and exporters requested the review. Therefore, pursuant to section 777(e)(2)(B) of the Tariff Act of 1930, as amended (the Act), we are conducting a review of all producers and exporters of subject merchandise covered by this order on the basis of aggregate data. This review covers 33 programs.

On May 1, 1996, we extended the period for completion of the preliminary and final results pursuant to section 751(a)(3) of the Act (*see Live Swine from Canada; Extension of Time Limit for Countervailing Duty Administrative Review,* 61 FR 19261). As explained in the memoranda from the Assistant Secretary for Import Administration to the File, dated November 22, 1995, and January 11, 1996 (on file in the Central Records Unit (CRU), Room B–099 of the Main Commerce Building), all deadlines were further extended to take into account the partial shutdowns of the Federal Government from November 15 through November 21, 1995, and December 15, 1995, through January 6, 1996. Therefore, the deadline for these preliminary results is no later than September 27, 1996, and the deadline for the final results of this review is no later than 180 days from the date on which these preliminary results are published in the Federal Register.

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions of the Tariff Act of 1930, as amended by the Uruguay Round Agreements Act (''URAA'') effective January 1, 1995. The Department is conducting this administrative review in accordance with section 751(a) of the Act. References to the *Countervailing Duties; Notice of Proposed Rulemaking and Request for Public Comments,* 54 FR 23366 (May 31, 1989) (*1989 Proposed Regulations*), are provided solely for further explanation of the Department's countervailing duty practice. Although the Department has withdrawn the particular rulemaking proceeding pursuant to which the *1989 Proposed Regulations* were issued, the subject matter of these regulations is being considered in connection with an ongoing rulemaking proceeding which, among other things, is intended to conform the Department's regulations to the URAA. *See Advance Notice of Proposed Rulemaking and Request for Public Comments,* 60 FR 80 (January 3, 1995); *Antidumping Duties; Countervailing Duties: Notice of Proposed Rulemaking and Request for Public Comments,* 61 FR 7308 (February 27, 1996).

Scope of the Review

On August 29, 1996, the *Final Results of Changed Circumstances Countervailing Duty Administrative Review, and Partial Revocation* were published (61 FR 45402), in which we revoked the order, in part, effective

April 1, 1991, with respect to slaughter sows and boars and weanlings (weanlings are swine weighing up to 27 kilograms or 59.5 pounds) from Canada, because this portion of the order was no longer of interest to domestic interested parties. As a result, the merchandise now covered by this order is live swine, except U.S. Department of Agriculture-certified purebred breeding swine, slaughter sows and boars, and weanlings, as defined above, from Canada. The merchandise subject to the order is classifiable under the *Harmonized Tariff Schedule* (HTS) item numbers 0103.91.00 and 0103.92.00. The HTS item numbers are provided for convenience and Customs purposes. The written description remains dispositive.

Verification

As provided in section 782(i) of the Act, we verified information submitted in the questionnaire responses. We followed standard verification procedures, including meeting with government officials and examination of relevant accounting and financial records and other original source documents. Our verification results are outlined in the public version of the *Verification Report,* which is on file in the CRU.

Allocation Methodology

In the past, the Department has relied upon information from the U.S. Internal Revenue Service (IRS) on the industry-specific average useful life of assets in determining the allocation period for nonrecurring grant benefits. *See General Issues Appendix* appended to *Final Countervailing Duty Determination; Certain Steel Products from Austria* (58 FR 37063, 37226; July 9, 1993). However, in *British Steel plc.* v. *United States,* 879 F. Supp. 1254 (CIT 1995) (*British Steel*), the U.S. Court of International Trade (the Court) ruled against this allocation methodology. In accordance with the Court's remand order, the Department calculated a company-specific allocation period for nonrecurring subsidies based on the average useful life (AUL) of non-renewable physical assets. This remand determination was affirmed by the Court on June 4, 1996. *British Steel,* 929 F. Supp. 426, 439 (CIT 1996).

The Department has decided to acquiesce to the Court's decision and, as such, we intend to determine the allocation period for nonrecurring subsidies using company-specific AUL data where reasonable and practicable. In this proceeding, the Department preliminarily determines that it is not reasonable and practicable to allocate nonrecurring grants using company-specific AUL data because it is not possible to apply a company-specific AUL in an aggregate case (such as the case at hand). On August 23, 1996, we requested comments on what the appropriate allocation methodology should be in an aggregate case. On September 3, 1996, we received one response from the National Pork Producers Council, petitioners, which urged the Department to continue using the three-year period set out in the IRS tax tables. Accordingly, the Department is using the original allocation period assigned to each grant. We invite the parties to comment on the selection of this methodology and provide any other reasonable and practicable approaches for complying with the Court's ruling.

Calculation Methodology for Assessment and Cash Deposit Purposes

For the period of review (POR), we calculated the net subsidy on a country-wide basis by first calculating the subsidy rate for each province subject to the administrative review. We then weight-averaged the rate received by each province using as the weight the province's share of total Canadian exports to the United States of subject merchandise. We summed the individual provinces' weight-averaged rates to determine the subsidy rate from all programs benefitting exports of the subject merchandise to the United States.

Analysis of Programs

I. Programs Conferring Subsidies

A. Programs Previously Determined to Confer Subsidies

1. Federal Program

Feed Freight Assistance Program

The Feed Freight Assistance Program (FFA) is administered by the Livestock Feed Board of Canada (the Board) under the Livestock Feed Assistance Act of 1966 (LFA). The Board acts to ensure: (1) the availability of feed grain to meet the needs of livestock feeders; (2) the availability of adequate storage space in Eastern Canada to meet the needs of livestock feeders; (3) reasonable stability in the price of feed grain in Eastern Canada to meet the needs of livestock feeders; and (4) equalization of feed grain prices to livestock feeders in Eastern Canada, British Columbia, the Yukon Territory and the Northwest Territories. Although this program is clearly designed to benefit livestock feeders, FFA payments are also made to grain mills that transform the feed grain into livestock feed whenever these mills are the first purchasers of this grain. The Board makes payments related to the cost of feed grain storage in Eastern Canada, and payments related to the cost of feed grain transportation to, or for the benefit of, livestock feeders in Eastern Canada, British Columbia, the Yukon Territory and the Northwest Territories, in accordance with the regulations of the LFA.

In *Live Swine from Canada; Preliminary Results of Countervailing Duty Administrative Review* (55 FR 20812; May 21, 1990) and *Live Swine from Canada; Final Results of Countervailing Duty Administrative Review* (56 FR 10410; March 12, 1991) (*Swine Second and Third Review Results*), the Department found this program *de jure* specific and thus countervailable because, based on the language of the LFA, benefits are only available to a specific group of enterprises or industries (livestock feeders and feed mills). Subsequently, a U.S.-Canada Free Trade Agreement (FTA) binational panel (*See In the Matter of Live Swine From Canada,* USA–91–1904–04 (June 11, 1993) at 33–36)) affirmed the Department's determination in *Live Swine from Canada; Preliminary Results of Countervailing Duty Administrative Review* (56 FR 29224) (June 26, 1991), and *Live Swine from Canada; Final Results of Countervailing Duty Administrative Review* (56 FR 50560; October 7, 1991) (*Swine Fifth Review Results*), regarding the countervailability of this program. No new information or evidence of changed circumstances has been submitted in this proceeding to warrant reconsideration of this finding.

To determine the FFA benefit in the POR, we used the methodology applied in *Live Swine from Canada; Preliminary Results of Countervailing Duty Administrative Review* (58 FR 54112, 54114; October 20, 1993)), and *Live Swine from Canada; Final Results of Countervailing Duty Administrative Review* (59 FR 12243; March 16, 1994)) (*Swine Sixth Review Results*). We first divided the amount of feed transportation assistance to live swine producers by the total weight of live swine produced in the FFA-eligible areas of Canada during the POR. We then weight-averaged the benefit by the corresponding provinces' share of total Canadian exports of live swine to the United States. On this basis, we preliminarily determine the benefits from this program to be Can$0.0006 per kilogram for the POR.

2. Federal/Provincial Programs

National Tripartite Stabilization Scheme for Hogs

The National Tripartite Stabilization Program (NTSP) was created in 1985 by an amendment to the Agricultural Stabilization Act (ASA). This amendment, codified at section 10.1 of the ASA, provides for the introduction of cost-sharing tripartite or bipartite stabilization schemes involving the producer, the federal government, and the provinces. Pursuant to this amendment, federal and provincial ministers signed NTSP agreements covering specific commodities.

The general terms of the NTSP for Hogs are as follows: all participating hog producers receive the same level of support per market-hog unit; the cost of the scheme is shared equally between the federal government, the provincial government, and the producers; producer participation in the scheme is voluntary; the provinces may not offer separate stabilization plans or other *ad hoc* assistance for hogs (with the exception of Quebec's FISI program); the federal government may not offer compensation to swine producers in a province not party to an agreement; and the scheme must operate at a level that limits losses but does not stimulate over-production.

Stabilization payments are made when the market price falls below the calculated support price. The difference between the support price and the market price is the amount of the stabilization payment. Hogs eligible for stabilization payments under NTSP must index above 80 on a hog carcass grading scale.

In *Swine Sixth Review Results* (58 FR 54115), the Department determined that NTSP was de facto specific because benefits were being provided to a specific enterprise or industry or group thereof. No new information or evidence of changed circumstances has been submitted in this proceeding to warrant reconsideration of this finding.

During the POR payouts were made to producers from sales that occurred in earlier fiscal years. (*See Verification Report* dated September 23, 1996, at page 4). To calculate the benefit, we first divided two-thirds (representing the federal and provincial portions) of the payments made during the POR to producers in each province by the total weight of market hogs produced in that province during the POR, and calculated a benefit per kilogram on a province-by-province basis. We then weight-averaged each exporting province's per-kilo benefit by that province's share of total Canadian exports of market hogs to the United States.

NTSP Agreement Amendment No. 3 terminated the plan as of July 2, 1994, but allowed provinces to terminate their participation in the plan effective April 2, 1994. The plan, which terminated prior to its originally scheduled termination date of December 31, 1995, ended with a surplus. Under the terms of the NTSP, this surplus was to be distributed in equal shares (33.3 percent) among the federal and provincial governments and the producers, because each was to have contributed one-third of the funds.

During verification, we examined the NTSP—Hogs Schedule of Operations (Schedule of Operations) which showed the federal and provincial governments' and the producers' contributions to the NTSP Hog Plan for the period January 1986 through May 29, 1996. This Schedule of Operations showed that the federal government contributed 36.6 percent and the producers and provinces contributed 31.7 percent each, of the total tripartite contributions during this ten-year period. Thus, the producers received a share of the surplus which is in excess of their actual contributions to the plan.

Accordingly, the Department preliminarily determines that the retroactive surplus payments constitute a benefit conferred under NTSP in the form of a grant to producers in the amount of the difference between what the producers actually are receiving, 33.3 percent of the surplus, and what they should have received, 31.7 percent of the surplus (the percentage producers actually contributed to NTSP). During the POR, producers received NTSP surplus payments in the following provinces which exported live swine: New Brunswick, Ontario, Manitoba, British Columbia, and Saskatchewan.

To calculate the subsidy, we subtracted the amount that the producer should have received (31.7 percent) from the amount that they actually received (33.3 percent). The difference is the amount of the grant. The Department's policy with respect to grants is (1) to expense recurring grants in the year of receipt, or (2) to allocate non-recurring grants over the average useful life of assets in the industry, unless the sum of grants provided under a particular program is less than 0.50 percent of a firm's total or export sales (depending on whether the program is a domestic or export subsidy) in the year in which the grants were received. (See section 355.49(a) of the *1989 Proposed Regulations* and the *General Issues Appendix*, at 37226). In determining whether a grant is recurring or non-recurring, we apply a test set out in the *General Issues Appendix* at 37226. We consider grants to be non-recurring if the benefits are exceptional, the recipient cannot expect to receive benefits on an ongoing basis from POR to POR, and the provision of funds by the government must be approved every year. In this case, while it is possible that some producers may receive additional residual benefits during a subsequent review period, these benefits would be exceptional rather than on an ongoing basis. Therefore, the Department preliminarily determines that this grant is non-recurring because the benefit is exceptional, and the recipient cannot expect to receive benefits on an ongoing basis.

However, because the amount received by live swine producers is less than 0.50 percent of the value of total live swine sales, we are allocating the benefit to the year of receipt. Therefore, we divided the benefit received by each province by the total weight of market hogs produced in that province. We used only the weight of market hogs because only market hogs were eligible to receive NTSP payments. We then weight-averaged the benefits by these provinces' share of total Canadian exports of market hogs to the United States during the POR. We then summed the benefit calculated for the residual payments and for the retroactive surplus. On this basis, we preliminarily determine the total benefit for the NTSP program to be Can$0.0172 per kilogram.

While the termination of the NTSP for Hogs constitutes a program-wide change, residual benefits may continue to be bestowed under this terminated program. For this reason, the cash deposit rate will not be adjusted as a result of the termination of this program. (19 CFR 355.50(1)(d) of the *1989 Proposed Regulations*).

3. Provincial Income Stabilization Programs

a. British Columbia Farm Income Insurance Program (FIIP)

The FIIP was established in 1979 in accordance with the Farm Income Insurance Act of 1973 (Farm Act) in order to assure income to farmers when commodity market prices fluctuate below the basic costs of production. Schedule B of the Farm Act lists the guidelines for the individual commodities receiving benefits; Schedule B section 4 is the guideline for swine producers.

The program is administered by the provincial Ministry of Agriculture and Food and the British Columbia

Federation of Agriculture and is funded equally by producers and the provincial government. Premiums are paid in all quarters regardless of market returns.

In *Swine Second and Third Review Results* (55 FR 20814), the Department found this program to be countervailable because the program is limited to producers of commodities listed in Schedule B, a specific group of enterprises or industries. No new information or evidence of changed circumstances has been submitted in these proceedings to warrant reconsideration of this finding.

Since the government of British Columbia funds one-half of this program, we calculated the benefit for the POR by dividing one-half of the total stabilization payments by the total weight of live swine produced in British Columbia. We then weight-averaged the result by British Columbia's share of total exports of live swine to the United States. On this basis, we preliminarily determine the benefit from this program to be less than Can$0.0001 per kilogram for the POR.

The FIIP was terminated effective July 2, 1994 to correspond with the termination of the NTSP for hogs. The last date for which a producer could claim benefits was June 30, 1994, and the last date by which payments could be received was December 31, 1994. Therefore, we consider this program terminated with no residual benefits and will not examine this program in the future. The termination of FIIP constitutes a program-wide change; and because there are no residual benefits, the cash deposit rate will be adjusted to zero for this program. (See 19 CFR 355.50(1)(d) of the 1989 *Proposed Regulations*).

b. Saskatchewan Hog Assured Returns Program (SHARP)

SHARP was established in 1976, pursuant to the Saskatchewan Agricultural Returns Stabilization Act which authorized provincial governments to establish stabilization plans for any agricultural commodity. SHARP provided income stabilization payments to hog producers in Saskatchewan when market prices fell below a designated ''floor price,'' calculated quarterly. The program was administered by the Saskatchewan Pork Producers' Marketing Board (the Board) on behalf of the Saskatchewan Department of Agriculture. The program was funded by levies from participating producers on the sale of hogs covered by the program; they ranged from 1.5 to 4.5 percent of market returns and were matched by the provincial government. When the balance in the SHARP account was insufficient to cover payments to producers, the provincial government provided financing on commercial terms. The principal and interest on these loans was to be repaid by the Board from the producer and provincial contributions. After the NTSP for Hogs was implemented on July 1, 1986, SHARP payments were reduced by the amount of the NTSP payments.

In *Swine First Review Results* (53 FR 22192, 22193), the Department found the SHARP program to be *de jure* specific, and thus countervailable, because the legislation expressly made the program available only to a single industry (hog producers). No new information or evidence of changed circumstances was submitted to warrant reconsideration of these findings.

In accordance with the NTSP agreement, SHARP was terminated on March 31, 1991. At the time of termination, the SHARP fund had a sizeable deficit because of the cumulation over the operating years of loans from the provincial government. During the 1993–94 POR, the government canceled the outstanding SHARP deficit. To calculate the benefit from the loan forgiveness, we treated one-half of the amount written off, plus interest accrued during the 1993–94 POR, as a grant in accordance with section 355.49(b)(1) of the *1989 Proposed Regulations.* We took into account only half of the amount because this was the share of the outstanding loans that the producers were responsible for repaying.

In *Live Swine from Canada; Notice of Preliminary Results of Countervailing Duty Administrative Reviews; Initiation and Preliminary Results of Changed Circumstances Review and Intent to Revoke Order in Part* (61 FR 26879; May 29, 1996) and *Live Swine from Canada; Final Results of Countervailing Duty Administrative Reviews,* which is being published concurrently with this notice (*Swine Seventh, Eighth, and Ninth*), the Department determined that the write-off of the SHARP deficit is a non-recurring grant because debt forgiveness is exceptional, and it is a one-time event. On this basis, we allocated the benefit from this grant over three years, which is the average useful life of depreciable assets used in the swine industry, as set out in the U.S. Internal Revenue Service Class Life Asset Depreciation Range System. We used, as a discount rate, the simple average of the monthly medium-term corporate bond rates (for the ninth POR, during which the write-off occurred) from the *Bank of Canada Review (1993–1994),* published by the Bank of Canada.

To calculate the benefit for the POR, we divided the benefit allocated to the POR under the grant allocation method by the total weight of market hogs produced in Saskatchewan during the POR to obtain the average benefit per kilogram. We then weight-averaged the per-kilogram benefit by Saskatchewan's share of total Canadian exports of market hogs to the United States during the POR. On this basis, we preliminarily determine the benefit to be Can$0.0028 per kilogram for the POR. While the termination of the SHARP constitutes a program-wide change, benefits from this terminated program will continue. For this reason, the cash deposit rate will not be adjusted as a result of the termination of this program. (19 CFR 355.50(1)(d) of the *1989 Proposed Regulations*).

4. Other Provincial Programs

a. Alberta Crow Benefit Offset Program (ACBOP)

This program, administered by the Alberta Department of Agriculture, is designed to compensate producers and users of feed grain for market distortions in feed grain prices, created by the federal government's policy on grain transportation. Assistance is provided for feed grain produced in Alberta, feed grain produced outside Alberta but sold in Alberta, and feed grain produced in Alberta to be fed to livestock on the same farm. The government provides ''A'' certificates to registered feed grain users and ''B'' certificates to registered feed grain merchants to use as partial payments for grain purchased from grain producers. Feed grain producers who feed their grain to their own livestock submit a Farm Fed Claim directly to the government for payment.

Hog producers receive benefits in one of three ways: hog producers who do not grow any of their own feed grain receive ''A'' certificates which are used to cover part of the cost of purchasing grain; hog producers who grow all of their own grain submit a Farm Fed Claim to the government of Alberta for direct payment; and hog producers who grow part of their own grain but also purchase grain receive both ''A'' certificates and direct payments.

In *Swine Second and Third Review Results* (56 FR 10412), the Department found this program to be *de jure* specific, and thus countervailable, because the legislation expressly makes it available only to a specific group of enterprises or industries (producers and users of feed grain). No new information or evidence of changed circumstances has been submitted in this proceeding to warrant reconsideration of this finding.

To determine the benefit to swine producers from this program, we followed the methodology used in *Swine Seventh, Eighth and Ninth Review Results.* Using the Alberta *Supply and Disposition Tables,* we first estimated the quantity of grain consumed by livestock in Alberta during the POR. Then, we multiplied the number of swine produced in Alberta during the POR by the estimated average grain consumption per hog, and divided the result by the amount of total grains used to feed livestock during the POR. We thus calculated the percentage of total livestock consumption of all grains in Alberta attributable to live swine during the POR. We then multiplied this percentage by the total value of ''A'' certificates and farm-fed claim payments received by producers during the POR. We divided this amount by the total weight of live swine produced in Alberta during the POR. We then weight-averaged this per-kilo benefit by Alberta's share of total Canadian exports of live swine to the United States. On this basis, we preliminarily determine the benefit to be Can$0.0009 per kilogram for the POR.

ACBOP was terminated on March 31, 1994. Benefits for ''A'' certificates had to be claimed by June 30, 1994, and benefits tied to farm-fed grains had to be claimed by August 31, 1994. Most claims have been paid, but there are some claims still outstanding. (*See Verification Report* at page 41). While the termination of the ACBOP program constitutes a program-wide change, residual benefits will continue to be bestowed under this program. For this reason, the cash deposit rate will not be adjusted as a result of the termination of this program. (19 CFR 355.50(1)(d) of the *1989 Proposed Regulations*).

b. Ontario Livestock and Poultry and Honeybee Compensation Program

This program, administered by the Farm Assistance Programs Branch of the Ontario Ministry of Agriculture, Food, and Rural Affairs, provides assistance in the form of grants which compensate producers for livestock and poultry injured or killed by wolves, coyotes, or dogs. Swine producers apply for and receive compensation through the local municipal government. The Ontario Ministry of Agriculture, Food, and Rural Affairs reimburses the municipality.

In *Swine Fifth Review Results* (56 FR 29227), the Department found this program to be *de jure* specific, and thus countervailable, because the legislation expressly makes it available only to a specific group of enterprises or industries (livestock and poultry farmers). No new information or evidence of changed circumstances has been submitted in this proceeding to warrant reconsideration of this finding.

To calculate the benefit, we used the methodology applied in *Swine Sixth Review Results* (58 FR 54119) and subsequent reviews. We divided the total payment to hog producers during the POR by the total weight of live swine produced in Ontario. We then weight-averaged the result by Ontario's share of Canadian exports of live swine to the United States during the POR. On this basis, we preliminarily determine the benefit from this program to be less than Can$0.0001 per kilogram for the POR.

c. Ontario Bear Damage to Livestock Compensation Program

This program, administered by the Farm Assistance Programs Branch of the Ontario Ministry of Agriculture, Food, and Rural Affairs, provides compensation for the destruction of, or injury to, certain types of livestock by bears. Swine producers apply for compensation through their local Ontario Ministry of Agriculture, Food, and Rural Affairs office. Local personnel then evaluate the damage and prepare a report. Based on this report and the farmer's application, the Livestock Commissioner may pay a grant to compensate for the amount of damage. Grants for damage to live swine cannot exceed Can$200 per head.

On January 14, 1991, during the fifth administrative review, petitioners submitted allegations of new programs, including the Bear Damage to Livestock Compensation Program, that may have provided countervailable benefits with respect to the production of live swine. However, in *Swine Fifth Review Results,* and subsequent reviews, the Department found this program not used. During the instant review, this program was used by producers of live swine. We preliminarily determine that this program is *de jure* specific, and thus countervailable, because the legislation expressly makes it available only to livestock producers, a specific group of enterprises or industries (cattle, goats, horses, sheep, swine, and poultry).

To calculate the benefit, we divided the total payment to hog producers during the POR by the total weight of live swine produced in Ontario. We then weight-averaged the result by Ontario's share of Canadian exports of live swine to the United States during the POR. On this basis, we preliminarily determine the benefit from this program to be less than Can$0.0001 per kilogram for the POR.

d. Ontario Export Sales Aid Program

The Ontario Export Sales Aid Program was established in 1987 to assist producers and processors of Ontario agricultural and food products to develop their export markets. This program is administered by the Ontario Ministry of Agriculture, Food and Rural Affairs which reimburses producers or processors for the costs they incur in developing their export marketing materials. Grants are made on a per-project basis, limited to two projects per producer or company, per fiscal year. The Ministry provides reimbursements for up to 50 percent of the project costs, with a maximum dollar amount. Producers submit a completed application form outlining the objectives of the market development plan, anticipated costs, and forecasted benefits to a review committee for approval. Upon approval, the producer or company receives the grant and initiates the project.

In *Swine Seventh, Eighth, and Ninth Review Results,* the Department determined this program to be a countervailable subsidy because receipt of benefits is contingent upon actual or anticipated exportation. The Department has also determined that these are non-recurring grants because the recipient cannot expect to receive benefits on an ongoing basis from review period to review period. In this review, because the amount received by live swine producers is less than 0.50 percent of the value of live swine exports from this province, we are allocating the benefit to the year of receipt.

To calculate the benefit received during the POR, we divided the total grant amount by the total weight of exports of live swine from Ontario during the POR. We then weight-averaged the result by Ontario's share of total exports of live swine to the United States during the POR. On this basis, we preliminarily determine the benefit from this program to be Can$0.0001 per kilogram.

e. Saskatchewan Livestock Investment Tax Credit

Saskatchewan's 1984 Livestock Tax Credit Act provides tax credits to individuals, partnerships, cooperatives, and corporations who owned and fed livestock marketed or slaughtered by December 31, 1989. Claimants had to be residents of Saskatchewan and pay Saskatchewan income taxes. Eligible claimants received credits of Can$3 for each hog. Although this program was terminated on December 31, 1989, tax credits are carried forward for up to

seven years. In *Swine First Review Results* (53 FR 22198), the Department found this program to be *de jure* specific, and thus countervailable, because the program's legislation expressly made it available only to livestock producers. No new information or evidence of changed circumstances has been submitted in this proceeding to warrant reconsideration of this finding.

To calculate the benefit for the POR, we used the methodology applied in *Swine Sixth Review Results* (58 FR 54120) and subsequent reviews. In the questionnaire responses, the GOC provided estimates of the amount of tax credits used by hog producers in Saskatchewan during the POR, since the actual amounts cannot be determined. At verification, we reviewed the methodology used to calculate these estimates and found it reasonable and consistent with that used in prior reviews. (*See Verification Report* at page 37). We divided the amount of benefit by the total weight of live swine produced in Saskatchewan during the POR. We then weight-averaged the result by Saskatchewan's share of total exports of live swine to the United States. On this basis, we preliminarily determine the benefit from this program to be Can$0.0001 per kilogram for the POR.

f. Saskatchewan Livestock Facilities Tax Credit

This program, which was terminated on December 31, 1989, provided tax credits to livestock producers based on their investments in livestock production facilities. The tax credits can only be used to offset provincial taxes and may be carried forward for up to seven years. Livestock covered by this program includes cattle, horses, sheep, swine, goats, poultry, bees, fur-bearing animals raised in captivity, or any other designated animals; covered livestock can be raised for either breeding or slaughter. Investments covered under the program include new buildings, improvements to existing livestock facilities, and any stationary equipment related to livestock facilities. The program pays 15 percent of 95 percent of project costs, or 14.25 percent of total costs.

In *Swine Second and Third Review Results* (55 FR 20820), the Department found this program to be *de jure* specific, and thus countervailable, because the program's legislation expressly made it available only to livestock producers. No new information or evidence of changed circumstances has been submitted in this proceeding to warrant reconsideration of this finding.

To calculate the benefit, we used the methodology applied in *Swine Sixth Review Results* (58 FR 54121) and subsequent reviews. In the questionnaire responses, the GOC provided estimates of the amount of tax credits used by hog producers in Saskatchewan, since the actual amounts cannot be determined. At verification, we reviewed the methodology used to calculate these estimates and found it reasonable and consistent with that used in prior reviews. (*See Verification Report* at page 37). We divided the amount of benefit by the total weight of live swine produced in Saskatchewan during the POR. We then weight-averaged the result by Saskatchewan's share of total exports of live swine to the United States. On this basis, we preliminarily determine the benefit from this program to be Can$0.0001 per kilogram for the POR.

g. Saskatchewan Interim Red Meat Production Equalization Program

The Saskatchewan Interim Red Meat Production Equalization Program (IRMPEP), administered by the Saskatchewan Department of Agriculture and Food, was established by the Government of Saskatchewan (GOS) in November 1992. IRMPEP provides grants to livestock producers who raise and feed their livestock in Saskatchewan. In order to qualify for IRMPEP, producers must have sold a minimum number of the eligible livestock which includes steers, heifers and virgin bulls, cull cows, hogs, lambs, kid goats, and horses. Once the minimum number of eligible livestock has been sold, the producer fills out an application and, if the criteria are met, is automatically eligible to receive grants under this program.

In *Swine Seventh, Eighth, and Ninth Review Results,* the Department found this program *de jure* specific, and thus countervailable, because the program's legislation expressly limits its availability to a specific group of enterprises or industries (livestock producers). No new information or evidence of changed circumstances has been submitted in this proceeding to warrant reconsideration of this finding.

The Department determined that these grants are recurring because the recipient can expect to receive benefits on an ongoing basis from POR to POR. (*See General Issues Appendix* (58 FR at 37226)). Therefore, to calculate the benefit, we have allocated the amounts of the grants to the year of receipt. Consequently, we divided the amount of IRMPEP grants to live swine producers for the POR by the total weight of live swine produced in Saskatchewan in the POR. We then weight-averaged the result by Saskatchewan's share of total exports of live swine to the United States during the POR. On this basis, we preliminarily determine the benefit from this program to be Can$0.0010 per kilogram for the POR.

Saskatchewan phased out the Interim Red Meat Production Equalization Program. The last date producers could apply for or claim benefits was November 30, 1994 and the last date that producers could receive benefits was March 31, 1995. Because IRMPEP has been terminated and there are no residual benefits being provided, the cash deposit rate will be adjusted to zero to reflect a program-wide change. (19 CFR 355.50(1)(d) of the *1989 Proposed Regulations*).

h. New Brunswick Livestock Incentives Program

This program, which operates under the Livestock Incentives Act, provides loan guarantees to livestock producers purchasing cattle, sheep, swine, foxes, and mink for breeding purposes, and for feeding and finishing livestock for slaughter. Loans, in amounts ranging from Can$1,000 to Can$90,000, are granted by commercial banks or credit unions and guaranteed by the Government of New Brunswick (GONB) to an individual, partnership, corporation or incorporated co-operative association engaged in farming in New Brunswick. Swine producers submit an application for a loan under this program to a bank. The bank evaluates the loan application based upon standard loan criteria and either approves or rejects the application. A consideration for obtaining the loan is the presentation to the GONB of a farm plan established at the time the loan is taken out. For loans given for the purchase of animals for breeding purposes, the term of the loan is not more than seven years and the first payment of the principal is due two years after the date on which the loan was given. For loans given for the purchase of animals for feeding purposes, the loan is due when the animals have been sold which shall not exceed a period of eighteen months. The interest rate for these loans is set at the prime rate plus one percentage point.

At the end of three years after loans are issued, the GONB may give 20 percent of the loan amount to the farmer in the form of a grant. To be eligible for this grant, the farmer had to have implemented, in a satisfactory manner, the farm plan established at the time the loan was taken out. The grant portion of

this program has been terminated. Grants are not provided for loans given after July 15, 1992, but grants were still being provided during the POR.

In *Swine Second and Third Review Results* (55 FR 20817), the Department found this program to be specific because it is limited to livestock producers. No new information or evidence of changed circumstances has been submitted in this proceeding to warrant reconsideration of this finding.

In accordance with section 771(5)(E)(iii) of the Act, a benefit from a loan obtained with a government guarantee shall normally be treated as conferred ''if there is a difference, after adjusting for any difference in guarantee fees, between the amount the recipient of the guarantee pays on the guaranteed loan and the amount the recipient would pay for a comparable commercial loan if there were no guarantee by the authority''. While there are no guarantee fees, the recipients are paying interest at the rate of prime rate plus one percentage point. As we learned at verification, the predominant lending rates in Canada for comparable long-term variable-rate loans are based on the prime rate plus a one or two-point spread. (*See Verification Report* at pages 9 and 22.) Therefore, as our benchmark, we used the prime rate as published by the Bank of Canada in the *Bank of Canada Review,* Winter 1995–96 plus one and one half percentage point. This rate represents the simple average of the spread above prime charged by commercial banks on comparable loans. Comparing the benchmark interest rate to the interest rate charged on these loans, we preliminarily determine that the amount the recipient paid on these loans is less than the recipient would have paid on a comparable commercial loan.

We calculated the benefit from the loan portion of this program as follows. For loans outstanding during the POR, either without repayments or paid off during the POR, we followed the methodology described in section 355.49 (d) (1) of the *1989 Proposed Regulations.* For outstanding loans on which partial repayments were made during the POR, because no information was available on the timing of the repayment, we estimated the benefit by taking half of the interest amount that would have accrued during the POR, had no payment been made on the principal. Next, we divided the benefit from all outstanding loans by the total weight of live swine produced in New Brunswick during the POR. We then weight-averaged the benefit by New Brunswick's share of Canadian exports of live swine to the United States during the POR.

During the POR loans to live swine producers were written-off by the GONB under this program. We have added to the total amount of written-off loans, the amount of interest accrued from the beginning of the POR until the date on which the loans were written-off. (*See* section 355.44(k) of the *1989 Proposed Regulations.*) The Department preliminarily determines that the amount written off and interest accrued during the POR is a non-recurring grant because debt forgiveness is exceptional, and it is a one-time event. In addition, swine producers received grants under the grant portion of this program. We preliminarily determine that the grants received under this program are non-recurring because the recipient cannot expect to receive benefits on an ongoing basis from year to year. We summed the amount of the written-off loans and the amount of the grants. Because the result is less than 0.50 percent of the value of live swine sales from this province, we are allocating the benefit to the year of receipt. (*See General Issues Appendix* 58 FR 37226.) Therefore, we divided the total amount of the grants provided during the POR by the total weight of live swine produced in New Brunswick during the POR. We then weight-averaged the result by the New Brunswick's share of total exports of live swine to the United States during the POR

To calculate the total benefit to live swine producers under this program, we summed the weight-averaged benefit calculated for the loans and grants. On this basis, we preliminarily determine the total benefit from this program to be less than Can$0.0001 per kilogram for this POR.

i. New Brunswick Swine Industry Financial Restructuring and Agricultural Development Act—Swine Assistance Program

The Swine Assistance program was established in fiscal year 1981–82, by the Farm Adjustment Board, under the Farm Adjustment Act, to provide interest subsidies on medium-term loans to hog producers. The program was available only to hog producers who entered production or underwent expansion after 1979. In 1985, the Farm Adjustment Act changed to the Agricultural Development Act. In 1984–85, this program was combined with the Swine Industry Financial Restructuring program under the New Brunswick Regulation 85–19. At that time, all obligations and outstanding loans under the Swine Assistance program were rolled over into the Swine Industry Financial Restructuring program.

The Swine Industry Financial Restructuring program was created by the Farm Adjustment Act (OC 85–98) and became effective April 1, 1985. Under this program the Government of New Brunswick granted hog producers indebted to the Board a rebate of the interest on that portion of their total debt (the residual debt) that, on March 31, 1984, exceeded the ''standard debt load.'' The standard debt load is defined in the program's regulations as the amount of debt which the farmer, in the opinion of the Board, can reasonably be expected to service. The residual debt does not begin to accrue interest again until the debt load is no longer ''excessive.''

In *Swine Second and Third Review Results* (55 FR 20816, 20817), the Department examined these two programs separately. The Department found (1) the Swine Assistance program to be countervailable because loans were provided to a specific industry on terms inconsistent with commercial considerations, and (2) the New Brunswick Swine Industry Financial Restructuring program to be countervailable because it was limited to a specific industry and the government's rebate of interest and the interest repayment holiday were loan terms inconsistent with commercial considerations. No new information or evidence of changed circumstances has been submitted in this proceeding to warrant reconsideration of this finding.

At verification, we examined documentation that showed that no new loans were provided for the past ten years, and that there was no recent activity on the outstanding loans. The loans given to producers were ''set aside'' in a provincial account and were not accruing any interest. The Department preliminarily determines that interest not accruing on the outstanding loan balance constitutes a benefit to live swine producers.

To calculate the benefit from this program, we multiplied the total outstanding debt at the beginning of the POR by the benchmark interest rate. We used, as a benchmark interest rate, the prime rate, as published by the Bank of Canada in the *Bank of Canada Review,* Winter 1994–95, plus one and one-half percentage point. This rate represents the simple average of the commercially available rates for comparable loans. (*See Verification Report* at page 22). Next, we divided the benefit by the total weight of live swine produced in New Brunswick during the POR. We then weight-averaged the benefit by New Brunswick's share of Canadian exports

of live swine to the United States during the POR. On this basis, we preliminarily determine the benefit to be less than Can$0.0001 per kilogram for the POR.

j. New Brunswick Swine Assistance Policy on Boars

The New Brunswick Swine Assistance Policy on Boars program is administered by the New Brunswick Department of Agriculture and Rural Development, Animal Industry Branch, for the purpose of encouraging breeding stock producers to produce quality boars at reasonable prices for use in commercial swine herds. This program provides assistance in the form of grants to swine producers for the purchases of boars. Eligible producers are entitled to receive up to Can$110 for the purchase of boars.

In *Swine Second and Third Review Results* (55 FR 20817), the Department found this program to be countervailable because it is limited to a specific industry. No new information or evidence of changed circumstances has been submitted in this proceeding to warrant reconsideration of this finding.

To calculate the benefit, we used the grant methodology applied in *Swine Sixth Review Results* (58 FR 54119). The Department has preliminarily determined that the grants received under this program are non-recurring because the recipient cannot expect to receive benefits on an ongoing basis from review period to review period. However, because the amount received by live swine producers in this POR is less than 0.50 percent of the value of live swine sales in this province, we are allocating the benefit to the year of receipt. (*See General Issues Appendix* 58 FR 37226). We divided the total payment to hog producers during the POR by the total weight of live swine produced in New Brunswick during the POR. We then weight-averaged the result by New Brunswick's share of Canadian exports of live swine to the United States during the POR. On this basis, we preliminarily determine the benefit from this program to be less than Can$0.0001 per kilogram for the POR.

B. New Programs Preliminarily Determined To Confer Subsidies

Federal/Provincial Programs

a. National Transition Scheme for Hogs

After termination of the NTSP for Hogs in July 1994, hog producers became eligible to participate in the National Transition Scheme for Hogs (Transition Scheme). This is a new program that provided for one-time payments to producers of hogs marketed between April 3, 1994 through December 31, 1994. This program was a temporary support program to encourage producers to join the Net Income Stabilization Account program (NISA). The Transition Scheme provided payments to hog producers of Can$1.50 per hog from the federal government and a matching Can$1.50 from the provincial government.

Because the Transition Scheme Agreement expressly limits its availability to a specific industry (swine), we preliminarily determine that the benefits from this program are *de jure* specific in accordance with section 771(5A)(D). The amounts provided by both the federal and provincial governments to the hog producers during the POR under the Transition Scheme represent a grant. Therefore, this program is countervailable.

The Department preliminarily determines that these grants are non-recurring because the transitional payments are exceptional, the recipient cannot expect to receive benefits on an ongoing basis from POR to POR, and the government has approved funding under the Transition Scheme for one year only. However, because the amount received by live swine producers is less than 0.50 percent of the value of total live swine sales in Canada, we are allocating the benefit to the year of receipt. Therefore, we divided the benefit provided during the POR to hog producers by the total weight of market hogs produced in that province, and calculated a benefit per-kilogram on a province-by-province basis. We used only the weight of market hogs because only market hogs were eligible to receive NTSP benefits. We then weight-averaged each exporting province's per kilogram benefit by that province's share of total Canadian exports of market hogs to the United States during the POR. On this basis, we preliminarily determine the benefit from this program to be Can$0.0042 per kilogram for the POR.

b. Technological Innovation Program Under the Canada/Quebec Subsidiary Agreement on Agri-Food Development (Agri-Food Agreement)

On December 14, 1984, the Government of Canada entered into an Economic and Regional Development Agreement (ERDA) with the Province of Quebec. Pursuant to this ERDA, the initial Agri-Food Agreement was signed on February 17, 1987 and remained in effect from 1987 to 1991. On August 26, 1993 a new Agri-Food Agreement was enacted by the governments of Canada and Quebec covering the period April 1, 1993 through March 31, 1998. Funding for this agreement is shared 50/50 by the federal and provincial governments. Through this agreement, grants are made to private businesses and academic organizations to fund projects in the following areas:

(1) Research: The objectives of this program area are to increase and diversify scientific and technical expertise, in both the industry and universities, in the areas of food production, processing, storage and marketing.

(2) Technological Innovation: The purpose of this program area is to speed up the rate of adoption and dissemination of technologies and innovation and the development of new products.

(3) Support for Strategic Alliances: The purpose of this program area is to stimulate cooperation and strategic alliances among the various stakeholders in an agri-food ''industry network'' (including all participants from the producer of the raw material to the final processor) through strategic activities intended to improve competitiveness in domestic and foreign markets.

Although the Agri-Food Agreement provides the authority for the three components, there are distinct differences in the purposes, funding, eligibility requirements and application and approval processes across the three components. Therefore, the Department considers it appropriate to examine each of the three components (Research, Technological Innovation, and Support for Strategic Alliances) as separate programs. *See* Memorandum on *Canada/Quebec Subsidiary Agreement on Agri-Food Development*, to Robert S. LaRussa from CVD/AD Team dated September 25, 1996, which is on file in the CRU.

We verified that during the POR, producers of live swine received grants under the Research Program and the Technological Innovation program. For a discussion of our preliminary determination with respect to the Research program, see Section II of this notice, ''New Programs Preliminarily Determined Not to Confer Subsidies.''

Technological Innovation Program

The Technological Innovation program is administered by the GOQ. This program has two components: testing and experimentation, and testing networks. Although the legislation states that ''the two governments will provide financial assistance and technical support to agricultural enterprises,'' we verified that since its inception this program has been funded solely by the federal government. Since assistance under this program is

provided by the federal government to industries located within a designated geographical region of Canada (*i.e.*, Quebec), we preliminarily determine that the federal contributions are countervailable. *See* section 771(5A)(D)(iv); Statement of Administrative Action accompanying the URAA, *reprinted* in H.R. Doc. No. 316, 103d Cong., 2d Sess. 932 (1994).

To calculate the benefit from this program, we preliminarily determine that the grants received under this program are non-recurring because they are exceptional, the government must approve the grants every year, and the recipient cannot expect to receive benefits on an ongoing basis. However, because the amount received by live swine producers in this POR is less than 0.50 percent of the value of live swine sales in this province, we are allocating the benefit to the year of receipt (*See General Issues Appendix* 58 FR 37226). We divided the total grant amount provided to swine producers during the POR by the total weight of live swine produced in Quebec during the POR. We then weight-averaged the results by Quebec's share of Canadian exports of live swine to the United States during the POR. On this basis, we preliminarily determine the benefit from the Technological Innovation program to be less than Can$0.0001 per kilogram for the POR.

II. Programs Preliminarily Determined Not to Confer Subsidies Research Program under the Canada/Quebec Subsidiary Agreement on Agri-Food Development (Agri-Food Agreement)

The Research program under the Agri-Food Agreement is administered by the Government of Quebec (GOQ) and grants are funded jointly by the GOQ and Government of Canada (GOC). The objectives of this program are to increase and diversify scientific and technical expertise, in both the industry and universities, in the area of food production, processing, storage and marketing. Under this program, grants are made to private businesses and academic organizations to fund research projects. During the POR, grants were provided for research projects involving live swine.

In the Department's questionnaire for this review, respondents were offered an opportunity to claim greenlight status under section 771(5B) of the Act. (*See* Department's Questionnaire, September 25, 1995, Section III.4 at III.4–2.) However, because the GOQ did not claim greenlight status, we proceeded to examine whether the results of the research are made publicly available. (*See* Section 355.44(l) of the *1989 Proposed Regulations*.) In this case, the results of research are usually made publicly available. We have verified that publication of the results of the research is required by the Agri-Food Agreement, which specifies that ''the Government of Canada and the Government of Quebec agree to announce jointly all authorized projects, as well as project and program reports and results.'' In addition, we have also verified that the results are published in an annual report upon completion. However, the Agreement also indicates, under Section 8 of the Research program guidelines, that participants have the right to patent protection for the results of the research if divulging the information will reduce the commercial value of those results. (*See Verification Report* at page 28.) Therefore, the determination of whether benefits under this program are countervailable can only be made at the completion of the projects. It is only upon completion that it will be known whether the results of research have been made publicly available. *See e.g., Final Affirmative Countervailing Duty Determinations: Certain Steel Products from Sweden* (58 FR 37385; July 9, 1993).

We verified that all projects involving live swine were still ongoing during the POR. Therefore, we will continue to examine these research grants in future reviews and upon completion will determine whether they are countervailable. On this basis, we preliminarily determine that the Research program did not confer countervailable benefits on live swine during the POR.

III. Programs Preliminarily Determined to be Not Used

We also examined the following programs and preliminarily determine that the producers and/or exporters of the subject merchandise did not apply for or receive benefits under these programs during the POR:

a. Quebec Farm Income Stabilization Insurance Program (FISI)

We verified that during the POR the only FISI payments made to producers were for live swine slaughtered in Canada. Because there were no payments made for live swine exported to the United States during the POR, we preliminarily determine that the FISI program was not used during the POR. *See* Memorandum to File from Team A regarding the *Farm Income Stabilization Program* dated September 25, 1996, which is on file in CRU.

b. Other Programs

(1) Support for Strategic Alliances Program under the Canada/Quebec Subsidiary Agreement on Agri-Food Development; (2) Western Diversification Program; (3) Federal Atlantic Livestock Feed Initiative; (4) Agricultural Products Board Program; (5) Ontario Rabies Indemnification Program; (6) Ontario Swine Sales Assistance Policy; (7) Newfoundland Hog Price Support Program; (8) Newfoundland Weanling Bonus Incentive Policy; (9) Newfoundland Hog Price Stabilization Program; (10) Nova Scotia Swine Herd Health Policy; (11) Nova Scotia Improved Sire Policy.

IV. Programs Preliminarily Determined to be Terminated

We have examined the following programs and preliminarily determine that they were terminated prior to April 1, 1994, and that no residual benefits were provided during the POR: (1) Alberta Livestock and Beeyard Compensation Program; (2) British Columbia Special Hog Payment Program; (3) British Columbia Swine Herd Improvement Program.

Preliminary Results of Review

We preliminarily determine the total net subsidy on live swine from Canada to be Can$0.0271 per kilogram for the period April 1, 1994 through March 31, 1995. If the final results of this review remain the same as these preliminary results, the Department intends to instruct the U.S. Customs Service (''Customs'') to assess countervailing duties as indicated above.

The Department also intends to instruct Customs to collect cash deposits of estimated countervailing duties of Can$0.0261 on all shipments of the subject merchandise from Canada, entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. We have adjusted the cash deposit rate to reflect program-wide changes.

Public Comment

Parties to the proceeding may request disclosure of the calculation methodology and interested parties may request a hearing not later than 10 days after the date of publication of this notice. Interested parties may submit written arguments in case briefs on these preliminary results within 30 days of the date of publication. Rebuttal briefs, limited to arguments raised in case briefs, may be submitted seven days after the time limit for filing the case brief. Parties who submit argument in this proceeding are requested to

submit with the argument (1) a statement of the issue and (2) a brief summary of the argument. Any hearing, if requested, will be held seven days after the scheduled date for submission of rebuttal briefs. Copies of case briefs and rebuttal briefs must be served on interested parties in accordance with 19 CFR § 355.38.

Representatives of parties to the proceeding may request disclosure of proprietary information under administrative protective order no later than 10 days after the representative's client or employer becomes a party to the proceeding, but in no event later than the date the case briefs, under 19 CFR § 355.38, are due. The Department will publish the final results of this administrative review, including the results of its analysis of issues raised in any case or rebuttal brief or at a hearing.

This administrative review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)).

Dated: September 25, 1996.

Robert S. LaRussa,

Acting Assistant Secretary for Import Administration.

[FR Doc. 96–25649 Filed 10–04–96; 8:45 am]

BILLING CODE 3510–DS–P

[C–122–815]

Pure Magnesium and Alloy Magnesium From Canada; Preliminary Results of Countervailing Duty Administrative Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of preliminary results of countervailing duty administrative reviews.

SUMMARY: The Department of Commerce (the Department) is conducting administrative reviews of the countervailing duty orders on pure and alloy magnesium from Canada. We preliminarily determine the net subsidy to be 4.01 percent *ad valorem* for Norsk Hydro Canada Inc. (NHCI) for the period January 1, 1994 through December 31, 1994. If the final results of these reviews remain the same as these preliminary results, the Department will instruct the U.S. Customs Service to assess countervailing duties as indicated above.

EFFECTIVE DATE: October 7, 1996.

FOR FURTHER INFORMATION CONTACT: Cynthia Thirumalai, AD/CVD Enforcement, Group 1, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482–4087.

Background

On August 1, 1995, the Department published in the Federal Register a notice of ''Opportunity to Request an Administrative Review'' (60 FR 39151) of the countervailing duty orders on pure and alloy magnesium from Canada (57 FR 39392 (August 31, 1992)). On August 16, 1995, Norsk Hydro Canada Inc. requested that the Department conduct administrative reviews of the countervailing duty orders. We initiated the reviews for the period January 1, 1994 through December 31, 1994, on September 15, 1995 (60 FR 47931). (See also Period of Review section below.)

On September 25, 1995, the Department issued questionnaires to NHCI, the Government of Canada (GOC), and the Government of Québec (GOQ). On October 10, 1995, the GOQ requested the Department re-issue its questionnaire, specifically identifying the sections meant to be answered by the GOQ. On October 17, 1995, the Department re-issued its questionnaire to the GOQ. The Department received questionnaire responses from NHCI, the GOC, and the GOQ on January 29, 1996.

On August 15, 1996, the Department issued a supplemental questionnaire to the GOQ, and, on August 20, 1996, the Department issued a supplemental questionnaire to NHCI. The Department received questionnaire responses from the GOQ and NHCI on September 10, 1996.

Applicable Statute and Regulations

The Department is conducting these administrative reviews in accordance with section 751(a) of the Tariff Act of 1930, as amended by the Uruguay Round Agreements Act (the Act). Unless otherwise indicated, all citations to the statute are references to the provisions of the Act. References to the Department's *Countervailing Duties; Notice of Proposed Rulemaking and Request for Public Comments,* 54 FR 23366 (May 31, 1989) (*Proposed Regulations*), are provided solely for further explanation of the Department's countervailing duty practice. Although the Department has withdrawn the particular rulemaking proceeding pursuant to which the *Proposed Regulations* were issued, the subject matter of these regulations is being considered in connection with an ongoing rulemaking proceeding which, among other things, is intended to conform the Department's regulations to the Uruguay Round Agreements Act (URAA). See 60 FR 80 (January 3, 1995).

Scope of the Review

The products covered by these reviews are pure and alloy magnesium from Canada. Pure magnesium contains at least 99.8 percent magnesium by weight and is sold in various slab and ingot forms and sizes. Magnesium alloys contain less than 99.8 percent magnesium by weight with magnesium being the largest metallic element in the alloy by weight, and are sold in various ingot and billet forms and sizes. Secondary and granular magnesium are not included. Pure and alloy magnesium are currently provided for in subheadings 8104.11.0000 and 8104.19.0000, respectively, of the Harmonized Tariff Schedule (HTS). Although the HTS subheadings are provided for convenience and Customs purposes, our written descriptions of the scopes of these proceedings is dispositive.

Period of Review

For purposes of calculating the net subsidy, the period of review (POR) is January 1, 1994 through December 31, 1994. NHCI accounted for all exports of subject merchandise during the period of review.

Analysis of Programs

I. Programs Previously Determined To Confer Subsidies

1. Exemption From Payment of Water Bills

Pursuant to a December 15, 1988 agreement between NHCI and La Société du Parc Industriel et Portuaire de Bécancour (Industrial Park), NHCI is exempt from payment of its water bills. Except for the taxes associated with its bills, NHCI does not pay the invoiced amounts of its water bills.

In the *Final Affirmative Countervailing Duty Determinations: Pure Magnesium and Alloy Magnesium from Canada (Magnesium from Canada)* 57 FR 30948 (July 13, 1992), the Department determined that the exemption received by NHCI was limited to a specific enterprise or industry, or group of enterprises or industries because no other company receives such an exemption. In this review, neither the GOQ nor NHCI provided new information which would warrant reconsideration of this determination.

We preliminarily determine the countervailable benefit to be the amount NHCI would have paid absent the exemption. To calculate the benefit under this program, we divided the amount NHCI would have paid for water during the POR by NHCI's total POR sales of Canadian-manufactured

products. On this basis, we preliminarily determine that the net subsidy provided by this program is 0.58 percent *ad valorem*.

2. Article 7 Grants from the Québec Industrial Development Corporation

The Société de Développement Industriel du Québec (SDI) administers development programs on behalf of the GOQ. SDI provides assistance under Article 7 of the SDI Act in the form of loans, loan guarantees, grants, assumptions of costs associated with loans, and equity investments. This assistance involves projects capable of having a major impact upon the economy of Québec. Article 7 assistance greater than 2.5 million dollars must be approved by the Council of Ministers, and assistance over 5 million dollars becomes a separate budget item under Article 7. Assistance provided in such amounts must be of ''special economic importance and value to the province.'' (See *Magnesium from Canada*, 57 FR 30949 (July 13, 1992).)

In 1988, NHCI was awarded a grant under Article 7 to cover a large percentage of the cost of certain environmental protection equipment. In *Magnesium from Canada*, we determined that NHCI received a disproportionately large share of assistance under Article 7. On this basis, we determined that the Article 7 grant was limited to a specific enterprise or industry, or group of enterprises or industries. In this review, neither the GOQ nor NHCI provided new information which would warrant reconsideration of this determination.

For the reasons set forth in *Magnesium from Canada*, we preliminarily determine that the grant provided under Article 7 was non-recurring because it represented a one-time provision of funds. (61 FR 11186 (March 19, 1996).)

We calculated the benefit from the grant received by NHCI using the company's cost of long-term, fixed-rate debt as the discount rate and our declining balance methodology, consistent with 355.49 of the *Proposed Regulations*. We divided that portion of the benefit allocated to the POR by NHCI's total sales of Canadian-manufactured products. (See the Allocation Methodology section below regarding the selection of the allocation period.) We preliminarily determine the net subsidy to be 3.43 percent *ad valorem* for NHCI.

II. Programs Preliminarily Found Not To Be Used

We preliminarily find that NHCI did not apply for or receive benefits under the following programs during the POR: St. Lawrence River Environment Technology Development Program, Program for Export Market Development, the Export Development Corporation, Canada-Québec Subsidiary Agreement on the Economic Development of the Regions of Québec, Opportunities to Stimulate Technology Programs, Development Assistance Program, Industrial Feasibility Study Assistance Program, Export Promotion Assistance Program, Creation of Scientific Jobs in Industries, Business Investment Assistance Program, Business Financing Program, Research and Innovation Activities Program, Export Assistance Program, Energy Technologies Development Program, and Transportation Research and Development Assistance Program.

Allocation Methodology

In the past, the Department has relied upon information from the U.S. Internal Revenue Service on the industry-specific average useful life of assets in determining the allocation period for non-recurring grant benefits. (See General Issues Appendix appended to *Final Countervailing Duty Determination; Certain Steel Products from Austria* (58 FR 37063, 37226 (July 9, 1993)).) However, in *British Steel plc.* v. *United States*, 879 F. Supp. 1254 (CIT 1995) (British Steel), the U.S. Court of International Trade (the Court) ruled against this allocation methodology. In accordance with the Court's remand order, the Department calculated a company-specific allocation period for non-recurring subsidies based on the average useful life (AUL) of non-renewable physical assets. This remand determination was affirmed by the Court on June 4, 1996 (British Steel, 929 F. Supp. 426, 439 (CIT 1996)).

The Department has decided to acquiesce to the Court's decision and, as such, we intend to determine the allocation period for non-recurring subsidies using company-specific AUL data where reasonable and practicable. Specifically, the Department has preliminarily determined that it is reasonable and practicable to allocate all new non-recurring subsidies (*i.e.*, subsidies that have not yet been assigned an allocation period) based on a company-specific AUL. However, if a subsidy has already been countervailed based on an allocation period established in an earlier segment of the proceeding, it does not appear reasonable or practicable to reallocate that subsidy over a different period of time. In other words, since the countervailing duty rate in earlier segments of the proceeding was calculated based on a certain allocation period and resulting benefit stream, redefining the allocation period in later segments of the proceeding would entail taking the original grant amount and creating an entirely new benefit stream for that grant. Such a practice may lead to an increase or decrease in the amount countervailed and, thus, would result in the possibility of over-countervailing or under-countervailing the actual benefit. The Department has preliminarily determined that a more reasonable and accurate approach is to continue using the allocation period first assigned to the subsidy. We invite the parties to comment on the selection of this methodology and provide any other reasonable and practicable approaches for complying with the Court's ruling.

In the current review, there are no new non-recurring grant subsidies. The non-recurring grant under review was provided prior to the POR; the allocation period for the grant was established during prior segments of these proceedings. Therefore, for purposes of these preliminary results, the Department is using the original allocation period assigned to the grant.

Preliminary Results of Review

We preliminarily determine the net subsidy for the period January 1, 1994 through December 31, 1994, to be 4.01 percent *ad valorem*.

Because the URAA replaced the general rule in favor of a country-wide rate with a general rule in favor of individual rates for investigated and reviewed companies, the procedures for establishing countervailing duty rates, including those for non-reviewed companies, are now essentially the same as those in antidumping cases, except as provided for in section 777A(e)(2)(B) of the Act. The requested review will normally cover only those companies specifically named. See section 355.22(a) of the *Interim Regulations*. Pursuant to 19 CFR 355.22(g), for all companies for which a review was not requested, duties must be assessed at the cash deposit rate, and cash deposits must continue to be collected, at the rate previously ordered. As such, the countervailing duty cash deposit rate applicable to a company can no longer change, except pursuant to a request for a review of that company. See *Federal-Mogul Corporation and The Torrington Company* v. *United States*, 822 F.Supp. 782 (CIT 1993) and *Floral Trade Council* v. *United States*, 822 F.Supp. 766 (CIT 1993) (interpreting 19 CFR 353.22(e), the antidumping regulation on automatic assessment, which is identical to 19 CFR 355.22(g)). Therefore, the case deposit rates for all

companies except those covered by this review will be unchanged by the results of this review.

We will instruct Customs to continue to collect cash deposits for non-reviewed companies at the most recent company-specific or country-wide rate applicable to the company. Accordingly, the cash deposit rates that will be applied to non-reviewed companies, except Timminco Limited (which was excluded from the order during the original investigation), covered by this order are those established in the most recently completed administrative proceeding. See 57 FR 30946. These rates shall apply to all non-reviewed companies until a review of a company assigned these rates is requested. In addition, for the period January 1, 1994 through December 31, 1994, the assessment rates applicable to all non-reviewed companies covered by this order are the cash deposit rates in effect at the time of entry.

If the final results of these reviews remain the same as these preliminary results, the Department intends to instruct the Customs Service to assess countervailing duties at 4.01 percent of the F.O.B. invoice price on all shipments by NHCI of the subject merchandise, exported on or after January 1, 1994 and on or before December 31, 1994. The Department also intends to instruct the Customs Service to collect a cash deposit of 4.01 percent on all shipments by NHCI of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of these administrative reviews.

Public Comment

Parties to these proceedings may request disclosure of the calculation methodology and interested parties may request a hearing not later than 10 days after the date of publication of this notice. Interested parties may submit written arguments in case briefs on these preliminary results within 30 days of the date of publication. Rebuttal briefs, limited to arguments raised in case briefs, may be submitted seven days after the time limit for filing the case brief. Parties who submit an argument in this proceeding are requested to submit with the argument (1) a statement of the issue, and (2) a brief summary of the argument. Any hearing, if requested, will be held seven days after the scheduled date for submission of rebuttal briefs. Copies of case briefs and rebuttal briefs must be served on interested parties in accordance with section 355.38 of the Department's Interim Regulations.

Representatives of parties to the proceeding may request disclosure of proprietary information under administrative protective order no later than 10 days after the representative's client or employer becomes a party to the proceeding, but in no event later than the date the case briefs, under 19 CFR 355.38, are due.

The Department will publish the final results of these administrative reviews, including the results of its analysis of issues raised in any case or rebuttal briefs or at a hearing, within 120 days of publication of this notice, according to 19 CFR 355.22(c)(7).

This administrative review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)).

Dated: September 25, 1996.

Robert S. LaRussa,

Acting Assistant Secretary for Import Administration.

[FR Doc. 96–25646 Filed 10–4–96; 8:45 am]

BILLING CODE 3510–DS–P

[C–301–003, C–301–601]

Roses and Other Fresh Cut Flowers and Miniature Carnations From Colombia

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Termination of reviews in progress for the 1995 annual review period.

SUMMARY: On August 30, 1996, the Department of Commerce published the final results of its countervailing duty administrative reviews and termination of suspended investigations (61 FR 45941). The reviews covered over 800 Colombian producers/exporters of roses, over 100 Colombian producers/exporters of miniature carnations and the Government of Colombia (''GOC'') for the period covering January 1, 1994 through December 31, 1994. These final results terminated the suspended investigation on roses and other cut flowers from Colombia and the suspended investigation on miniature carnations from Colombia, effective August 30, 1996, and announced our intention to terminate the reviews in progress for these agreements covering the January 1, 1995 through December 31, 1995 period.

EFFECTIVE DATE: October 7, 1996.

FOR FURTHER INFORMATION CONTACT: N. Gerard Zapiain at (202) 482–0190 or Jean Kemp at (202) 482–4037 at Antidumping/Countervailing Enforcement, International Trade Administration, U.S. Department of Commerce, Washington, D.C. 20230.

Background

After considering comments received in connection with the 1994 annual review, we determined that the GOC and the producers/exporters of the subject merchandise had complied with all the terms of the suspension agreements during the review period. Therefore, we determined that the GOC and the producers/exporters covered by these agreements had met the requirements for termination of this suspended countervailing duty investigations on roses and other cut flowers required by 19 CFR 355.25. We, therefore, decided to terminate the suspended investigation on roses and other cut flowers from Colombia and the suspended investigation on miniature carnations from Colombia, effective August 30, 1996. As a result of this determination, we are terminating the reviews in progress for these agreements covering the 1995 period.

This notice is in accordance with sections 751(a)(1)(C) of the Tariff Act (19 U.S.C. 1675(a)(1)(C)) and 19 CFR 355.22 and 355.25.

Dated: September 27, 1996.

Barbara Stafford,

Acting Assistant Secretary for Import Administration.

[FR Doc. 96–25645 Filed 10–4–96; 8:45 am]

BILLING CODE 3510–DS–P

National Oceanic and Atmospheric Administration

[I.D. 092796H]

Gulf of Mexico Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will convene a public meeting of the Shrimp Advisory Panel (AP).

DATES: This meeting will be held on October 28, 1996, from 8:00 a.m. to 5:00 p.m.

ADDRESSES: This meeting will be held at the Grand Casino, 265 Beach Boulevard, Biloxi, MS 39530; telephone 800–946–2946.

Council address: Gulf of Mexico Fishery Management Council, 5401 West Kennedy Boulevard, Suite 331, Tampa, FL 33609.

FOR FURTHER INFORMATION CONTACT: Dr. Richard L. Leard, Senior Fishery Biologist; telephone: 813–228–2815.

SUPPLEMENTARY INFORMATION: The purpose of the meeting will be to review Draft Amendment 9 to the Fishery Management Plan for the Shrimp Fishery of the Gulf of Mexico, U.S. Waters with Supplemental Environmental Impact Statement (SEIS), Regulatory Impact Review (RIR), Initial Regulatory Flexibility Analysis (IRFA), and Social Impact Assessment (SIA). The amendment addresses the Council's commitment to reduce the bycatch mortality of juvenile red snapper from shrimp trawls. The amendment includes a review of previous actions and their effects on bycatch as well as various alternatives.

The AP will review the draft amendment with various management alternatives for bycatch reduction including the Council's ''preferred alternatives.'' Measures being considered include: (1) Status Quo - no change to existing regulations; and (2) Require the installation of Bycatch Reduction Devices (BRDs) in all trawls used in the penaeid shrimp fishery of the Exclusive Economic Zone (EEZ). They will also review area specific usage of BRDs including requiring BRDs: (1) inside the 100–fathom contour; (2) inside the 100–fathom contour and west of Cape San Blas, FL; (3) between the 10– and 100–fathom contours; and (4) between the 10– and 100–fathom contours and west of Cape San Blas, FL. Other alternatives that will be discussed include: bycatch reduction criteria; seasonal closures; and a framework procedure for modifying bycatch reduction criteria, BRD certification, and testing requirements. The Shrimp AP will also consider an RIR, which mainly reviews the economic ramifications of the proposed amendment; an SIA; and any environmental consequences. Also considered will be the effects of other Federal laws and regulations.

The AP is comprised of fisherman and other user groups who advise the Council on fishery issues.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Anne Alford at the Council (see **ADDRESSES**) by October 21, 1996.

Dated: September 30, 1996.

Bruce Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 96–25588 Filed 10–4–96; 8:45 am]

BILLING CODE 3510–22–F

[I.D. 092796I]

Gulf of Mexico Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will convene a public meeting of the Red Snapper Advisory Panel (AP).

DATES: This meeting will be held on October 31, 1996 from 8:30 a.m. to 4:00 p.m.

ADDRESSES: This meeting will be held at the Grand Casino, 265 Beach Boulevard, Biloxi, MS 39530; telephone: (800) 946–2946.

Council address: Gulf of Mexico Fishery Management Council, 5401 West Kennedy Boulevard, Suite 331, Tampa, FL 33609.

FOR FURTHER INFORMATION CONTACT: Steven Atran, Population Dynamics Statistician; telephone: (813) 228–2815.

SUPPLEMENTARY INFORMATION: The purpose of the meeting will be to review the Reef Fish Stock Assessment Panel (RFSAP) and Socioeconomic Panel (SEP) reports regarding a new stock assessment for vermilion snapper, an update of the 1995 stock assessment for red snapper, and discussions regarding biological information and landings data for amberjack species. The AP will review any recommendations of the RFSAP and SEP regarding allowable biological catch (ABC) ranges for these species, and they may develop recommendations of ABC or total allowable catch (TAC) for submission to the Council. The AP may also recommend future data gathering and research needs.

Under the Reef Fish Fishery Management Plan's framework procedure for setting TAC, when an ABC range has been specified, the Council may implement through a regulatory amendment a TAC, which is then allocated between the recreational and commercial sectors, and quotas, bag limits, size limits, and other measures needed to attain TAC. If an ABC range and TAC are not specified, the Council must use the more lengthy process of a full plan amendment to implement any changes to management measures.

The AP is comprised of fisherman and other user groups who advise the Council on fishery issues.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Anne Alford at the Council (see **ADDRESSES**) by October 21, 1996.

Dated: September 30, 1996.

Bruce Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 96–25589 Filed 10–4–96; 8:45 am]

BILLING CODE 3510–22–F

[I.D. 092796J]

Gulf of Mexico Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will convene a public meeting.

DATES: The meetings are scheduled as follows: Standing and Special Shrimp Scientific and Statistical Committee (SSC), October 29, 1996, 8:00 a.m. to 5:00 p.m.; Standing and Special Reef Fish Scientific and Statistical Committee (SSC), October 30, 1996, 8:00 a.m. to 5:00 p.m.

ADDRESSES: The meetings will be held at the Grand Casino, 265 Beach Boulevard, Biloxi, MS 39530; telephone: 800–946–2946.

Council address: Gulf of Mexico Fishery Management Council, 5401 West Kennedy Boulevard, Suite 331, Tampa, FL 33609.

FOR FURTHER INFORMATION CONTACT: Dr. Richard L. Leard, Senior Fishery Biologist; telephone: 813–228–2815.

SUPPLEMENTARY INFORMATION: On October 29, beginning at 8:00 a.m., the Shrimp SSC will review Draft Amendment 9 to the Fishery Management Plan for the Shrimp Fishery of the Gulf of Mexico, U.S. Waters with Supplemental Environmental Impact Statement (SEIS), Regulatory Impact Review (RIR), Initial Regulatory Flexibility Analysis (IRFA), and Social Impact Assessment (SIA). The amendment addresses the Council's commitment to reduce the bycatch mortality of juvenile red snapper from

shrimp trawls. The amendment includes a review of previous actions and their effects on bycatch as well as various alternatives.

The Shrimp SSC will review the draft amendment which includes various management alternatives for bycatch reduction, including the Council's ''preferred alternatives.'' Measures being considered include: (1) Status Quo - no change to existing regulations; and (2) Require installation of Bycatch Reduction Devices (BRDs) in all trawls used in the penaeid shrimp fishery in the Exclusive Economic Zone (EEZ), except test or try nets. They will also review area-specific usage of BRDs, including requiring BRDs: (1) inside the 100–fathom contour; (2) inside the 100–fathom contour and west of Cape San Blas, FL; (3) between the 10– and 100–fathom contours, and (4) between the 10– and 100–fathom contours and west of Cape San Blas, FL. Other alternatives that will be discussed include: bycatch reduction criteria; seasonal closures; a framework procedure for modifying bycatch reduction criteria, BRD certification, and testing requirements. The Shrimp SSC will also consider an RIR, which mainly reviews the economic ramifications of the proposed amendment; an SIA; and any environmental consequences. Also considered will be the effects of other Federal laws and regulations.

On October 30, beginning at 8:00 a.m. the Reef Fish SSC will review Reef Fish Stock Assessment Panel (RFSAP) and Socioeconomic Panel (SEP) reports regarding a new stock assessment for vermilion snapper, an update of the 1995 stock assessment for red snapper, and discussions regarding biological information and landings data for amberjack species. The SSC will review any recommendations of the RFSAP and SEP regarding allowable biological catch (ABC) ranges for these species, and they may develop recommendations of ABC or total allowable catch (TAC) for submission to the Council. The SSC may also recommend future data gathering and research needs.

Under the Reef Fish Fishery Management Plan's framework procedure for setting TAC, when an ABC range has been specified, the Council may implement through a regulatory amendment a TAC, which is then allocated between the recreational and commercial sectors, and quotas, bag limits, size limits, and other measures needed to attain TAC. If an ABC range and TAC are not specified, the Council must use the more lengthy process of a full plan amendment to implement any changes to management measures.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Anne Alford at the Council (see **ADDRESSES**) by October 21, 1996.

Dated: September 30, 1996.

Bruce Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 96–25590 Filed 10–4–96; 8:45 am]

BILLING CODE 3510–22–F

[I.D. 092796F]

Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council (Council) and its advisory entities will hold public meetings.

DATES: The meetings will be held on October 20–25, 1996. See **SUPPLEMENTARY INFORMATION** for specific dates and times.

ADDRESSES: The meetings will be held at the South San Francisco Conference Center, 255 South Airport Boulevard, South San Francisco, CA 94080; telephone: (415) 873–3550.

Council address: Pacific Fishery Management Council, 2130 SW Fifth Avenue, Suite 224, Portland, OR 97201.

FOR FURTHER INFORMATION CONTACT: Lawrence D. Six, Executive Director, Pacific Fishery Management Council, 2130 SW Fifth Avenue, Suite 224, Portland, OR; telephone: (503) 326–6352.

SUPPLEMENTARY INFORMATION: On October 21, at 1:00 p.m., a workshop on the salmon plan amendment scoping process will begin. Members of the Council, advisory groups, and the public are encouraged to participate in an informal process to discuss potential amendments to the salmon fishery management plan. The entire group will meet in a plenary session at 1:00 p.m. on October 21, to discuss the process and then two discussion groups will convene for the rest of the day.

The Council meeting will begin on October 22, at 8:00 a.m. in a closed session (not open to the public) to discuss litigation. The open session begins at 8:30 a.m. The Council meeting reconvenes at 8:00 a.m. on October 23, and will adjourn when Council business has been completed.

The following items are on the Council agenda:

A. Call to Order

B. Habitat Issues

1. Report of the Habitat Steering Group.

C. Groundfish Management

1. Final Harvest Levels and Other Specifications for 1997;
2. California Gillnet Regulations in the Exclusive Economic Zone;
3. Status of Federal Regulations Implementing Council Actions;
4. Status of Fisheries and Inseason Adjustments;
5. Limited Entry Fixed Gear Sablefish Harvest Regime for 1997;
6. Trip Limits, Bag Limits and Other Measures for 1997;
7. Pacific Whiting Allocation, Season Framework and Salmon Bycatch;
8. Experimental Fishing Permits for Shore-based Whiting Fishery Data Collection;
9. Restrictions on Limited Entry Permit Transfers;
10. Landing and Disposition of Fish Exceeding Trip Limits;
11. GMT Report on Scoping Process;
12. Review of New Stock Assessment Process; and
13. Appointment of Ad Hoc Committee to Address At-Sea Processing of Fish Other Than Whiting.

D. Pacific Halibut Management

1. Summary of 1996 Fisheries;
2. Changes to the Catch Sharing Plan and Sport Regulations for 1997; and
3. Report of the IPHC on Bycatch Compensation and Stock Assessment.

E. Salmon Management

1. Sequence of Events and Status of Fisheries;
2. Final report on 1996 Methodology Reviews;
3. Annual State Agency and Tribal Reports on Activities to Restore Natural Stocks;
4. Endangered Species Act Standards for 1997 Fisheries;
5. Plan Amendments;
Management Objectives for Listed Species
Salmon Bycatch in Whiting Fisheries
Update of Framework Plan
6. Status of Revisions to Oregon Coastal Natural (Coho) Escapement Goal; and
7. Scoping for Future Plan Amendments.

F. Administrative and Other Matters

1. Report of Council/NMFS Working Group Meeting;

2. Budget Committee Report - ACTION;

3. Status of Legislation;

4. Appointments to Scientific and Statistical Committee, Advisory Panel - ACTION;

5. Response to Council Research Needs;

6. Work Load Priorities for 1997; and

7. Draft Agenda for March 1997 - ACTION.

Other meetings:

The Groundfish Subcommittee of the Scientific and Statistical Committee will meet on October 20, at 7:00 p.m.

The Groundfish Management Team will convene on October 21, at 8 a.m., to address groundfish management items on the Council agenda.

The Scientific and Statistical Committee will convene on October 21, at 8:00 a.m. and October 22, at 8:00 a.m., to address scientific issues related to Council agenda items.

The Habitat Steering Group will convene on October 21, at 10:00 a.m.

The salmon plan amendment discussion groups will convene on October 21, to discuss potential amendments to the salmon fishery management plan.

The Groundfish Advisory Subpanel will convene on October 22, at 8:00 a.m. and will continue to meet on October 23, and if necessary, on October 24.

The Salmon Advisory Subpanel will convene on October 22, at 8:00 a.m., if necessary.

The Salmon Technical Team will convene on October 22, at 8:00 a.m., if necessary.

The California Department of Fish and Game will conduct an evening presentation on the recreational salmon hook and release mortality study conducted near San Francisco in 1996 on October 22, at 7:00 p.m.

The Budget Committee will convene on October 24 for a lunch meeting, (time to be determined).

The Enforcement Consultants meet on October 22, at 7:00 p.m., to address enforcement issues related to Council agenda items.

Detailed agendas for the above advisory meetings will be available after September 27, 1996.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Eric W. Greene at (503) 326–6352 at least 5 days prior to the meeting date.

Dated: September 30, 1996.

Bruce Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 96–25591 Filed 10–4–96; 8:45 am]

BILLING CODE 3510–22–F

[I.D. 092796G]

Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council's (Council) Scientific and Statistical Committee Salmon Subcomittee will hold a public meeting.

DATES: The meeting will begin on October 15, 1996, at 8:00 a.m. The meeting will reconvene at 8:00 a.m. on October 16, and will adjourn when business has been completed.

ADDRESSES: The meeting will be held at the Red Lion Hotel Sea-Tac Airport, Olympic III Room, 18740 Pacific Highway South, Seattle, WA 96188; telephone: (206) 246–8600.

Council address: Pacific Fishery Management Council, 2130 SW Fifth Avenue, Suite 224, Portland, OR 97201.

FOR FURTHER INFORMATION CONTACT: Jim Seger, Economic Analysis Coordinator; telephone: (503) 326–6352.

SUPPLEMENTARY INFORMATION: The primary purpose of this meeting is to review methodologies used by the Council to manage salmon.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Eric W. Greene at (503) 326–6352 at least 5 days prior to the meeting date.

Dated: September 30, 1996.

Bruce Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 96–25592 Filed 10–4–96; 8:45 am]

BILLING CODE 3510–22–F

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Director, Information Resources Group, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: An emergency review has been requested in accordance with the Act (44 U.S.C. Chapter 3507(j)), since public harm is reasonably likely to result if normal clearance procedures are followed. Approval by the Office of Management and Budget (OMB) has been requested by October 7, 1996. A regular clearance process is also beginning. Interested persons are invited to submit comments on or before December 7, 1996.

ADDRESSES: Written comments regarding the emergency review should be addressed to the Office of Information and Regulatory Affairs, Attention: Wendy Taylor, Desk Officer: Department of Education, Office of Management and Budget, 725 17th Street, N.W., Room 10235, New Executive Office Building, Washington, D.C. 20503. Requests for copies of the proposed information collection request should be addressed to Patrick J. Sherrill, Department of Education, 7th & D Streets, S.W., Room 5624, Regional Office Building 3, Washington, D.C. 20202–4651. Written comments regarding the regular clearance and requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, S.W., Room 5624, Regional Office Building 3, Washington, D.C. 20202–4651, or should be electronically mailed to the Internet address #FIRB@ed.gov, or should be faxed to 202–708–9346.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction act of 1995 (44 U.S.C. Chapter 3506(c)(2)(A)) requires that the Director of OMB provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The Office of Management and Budget (OMB) may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its

statutory obligations. The Director of the Information Resources Group publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. ED invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department, (2) will this information be processed and used in a timely manner, (3) is the estimate of burden accurate, (4) how might the Department enhance the quality, utility, and clarity of the information to be collected, and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: October 1, 1996.

Gloria Parker,

Director, Information Resources Group.

Office of Educational Research and Improvement

Type of Review: New.

Title: Early Childhood Longitudinal Survey—Fall Assessment Activities and Parent Interview.

Frequency: One time.

Affected Public: Individuals or households; Not-for-profit institutions.

Reporting Burden and Recordkeeping:

Responses: 2,800.

Burden Hours: 1,437.

Abstract: This emergency clearance request is for the Parent Interview Component and the assessment activities to take place in October 1996. It is made in order to begin these activities pending the clearance of all Early Childhood Longitudinal Study field test activities that are in the process currently. The parent interviews will supplement the actual assessments of kindergartners, providing parental assessment of their children at the beginning of kindergarten, and information about parent involvement and children's background.

[FR Doc. 96–25585 Filed 10–4–96; 8:45 am]

BILLING CODE 4000–01–M

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Submission for OMB review; comment request.

SUMMARY: The Director, Information Resources Group, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before November 6, 1996.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Wendy Taylor, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection requests should be address to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, SW., Room 5624, Regional Office Building 3, Washington, DC 20202–4651.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Director of the Information Resources Group publishes this notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

Dated: October 1, 1996.

Gloria Parker,

Director, Information Resources Group.

Office of Educational Research and Improvement

Type of Review: Revision.

Title: Integrated Postsecondary Education Data System (IPEDS) 1996 through 1997/1998.

Frequency: Annually.

Affected Public: Business or other for-profit; Not-for-profit institutions; State, local or Tribal Governments, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 10,114.

Burden Hours: 37,174.

Abstract: The IPEDS provides information on postsecondary education—it's provides, enrollments, completions, and finances in addition to other information. The recent publication of final regulations for Student Right-to-Know and changes in financial accounting standards for nonprofit changes in financial accounting standards for nonprofit institutions have made it necessary for NCES to modify the IPEDS data collection for 1996 and 1997 to help institutions adapt to these changes.

Office of Management

Type of Review: Reinstatement.

Title: Customer Service Standards and Focus Groups.

Frequency: One Time.

Affected Public: Individuals or households; Business or other for-profit; Not for Profit institutions; Federal Government; State, Local or Tribal Government, SEAs or LEAs.

Annual Reporting and Recordkeeping Hour Burden:

Responses: 200,500.

Burden Hours: 101,500.

Abstract: Thee focus groups will be used to measure customer satisfaction and to improve customer service standards in compliance with Executive Order 12862.

[FR Doc. 96–25556 Filed 10–4–96; 8:45 am]

BILLING CODE 4000–01–M

Federal Interagency Coordinating Council Meeting (FICC)

AGENCY: Federal Interagency Coordinating Council, Education.

ACTION: Notice of a public meeting.

SUMMARY: This notice describes the schedule and agenda of a forthcoming

meeting of the Federal Interagency Coordinating Council. Notice of this meeting is required under section 685(c) of the Individuals with Disabilities Education Act, as amended, and is intended to notify the general public of their opportunity to attend the meeting. The meeting will be accessible to individuals with disabilities.

DATE AND TIME: October 7, 1996, from 1:45 p.m. to 5:00 p.m.

ADDRESS: Hyatt Regency Washington on Capitol Hill, 400 New Jersey Avenue, NW., Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Connie Garner, U.S. Department of Education, 600 Independence Avenue, SW., Room 3127, Switzer Building, Washington, DC 20202–2644. Telephone: (202) 205–8124. Individuals who use a telecommunications device for the deaf (TDD) may call (202) 205–8170.

SUPPLEMENTARY INFORMATION: The Federal Interagency Coordinating Council (FICC) is established under section 685 of the Individuals with Disabilities Education Act, as amended (20 U.S.C. 1484a). The Council is established to: (1) Minimize duplication across Federal, State and local agencies of programs and activities relating to early intervention services for infants and toddlers with disabilities and their families and preschool services for children with disabilities; (2) ensure effective coordination of Federal early intervention and preschool programs, including Federal technical assistance and support activities; and (3) identify gaps in Federal agency programs and services and barriers to Federal interagency cooperation. To meet these purposes, the FICC seeks to: (1) Identify areas of conflict, overlap, and omissions in interagency policies related to the provision of services to infants, toddlers, and preschoolers with disabilities; (2) develop and implement joint policy interpretations on issues related to infants, toddlers, and preschoolers that cut across Federal agencies, including modifications of regulations to eliminate barriers to interagency programs and activities; and (3) coordinate the provision of technical assistance and dissemination of best practice information. The FICC is chaired by the Assistant Secretary for Special Education and Rehabilitative Services.

At this meeting the FICC plans to: (1) Review the accomplishments of the FICC; and (2) discuss issues related to the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

The meeting of the FICC is open to the public. Written public comment will be accepted at the conclusion of the meeting. These comments will be included in the summary minutes of the meeting. The meeting will be physically accessible with meeting materials provided in both braille and large print. Interpreters for persons who are hearing impaired will be available. Individuals with disabilities who plan to attend and need other reasonable accommodations should contact the contact person named above in advance of the meeting.

Summary minutes of the FICC meetings will be maintained and available for public inspection at the U.S. Department of Education, 600 Independence Avenue, SW., Room 3127, Switzer Building, Washington, DC 20202–2644, from the hours of 9:00 a.m. to 5:00 p.m., weekdays, except Federal holidays.

Judith E. Heumann,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 96–25614 Filed 10–4–96; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP96–777–000]

Northern Natural Gas Company; Notice of Request Under Blanket Authorization

October 1, 1996.

Take notice that on September 10, 1996, Northern Natural Gas Company (Northern), 1111 South 103rd Street, Omaha, Nebraska 68124–1000, filed and supplemented on September 26, 1996, in Docket No. CP96–777–000 a request pursuant to Sections 157.205 157.212 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.212, 157.216) for authorization to upgrade two existing delivery points located in Sarpy County, Nebraska and Polk County, Iowa under Northern's blanket certificate issued in Docket No. CP82–401–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Northern proposes to upgrade two existing delivery points. Northern also requests authorization to retire the meters and appurtenant facilities associated with the subject delivery points. Northern states that no throughput service is being abandoned. The upgrade will accommodate increased natural gas deliveries to UtiliCorp United, Inc. (UCU). Northern asserts that UCU has requested the increased service at the delivery points to accommodate growth in the area.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 96–25572 Filed 10–4–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP96–816–000]

Northern Natural Gas Company; Notice of Request Under Blanket Authorization

October 1, 1996.

Take notice that on September 27, 1996, Northern Natural Gas Company (Applicant), P.O. Box 3330, Omaha, Nebraska 68103 filed in Docket No. CP96–816–000 for approval under Section 157.205 and 157.212 to install and operate a new delivery point at the City of Humbolt, a local municipal utility, for redelivery to the community of Humbolt, South Dakota, all as more fully described in the application which is on file with the Commission and open to public inspection.

Applicant states that volumes proposed for delivery to the City of Humbolt are 1,494 MMBtu on a peak day and 49,414 MMBtu on an annual basis. Northern states that the cost to install the delivery point is $77,000.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a

protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 96–25574 Filed 10–4–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP96–813–000]

Texas Gas Transmission Corporation; Notice of Request Under Blanket Authorization

October 1, 1996.

Take notice that on September 24, 1996, Texas Gas Transmission Corporation (Texas Gas), 3800 Frederica Street, Owensboro, Kentucky 424301 filed in Docket No. CP96–813–000 a request pursuant to Sections 157.205, 157.212, and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.212, and 157.216) for approval and permission to modify an existing delivery point, construct and operate a new delivery point, and abandon certain facilities by sale to Indiana Gas Company, Inc. (Indiana Gas) in Vigo and Lawrence Counties, Indiana, under the blanket certificate issued in Docket No. CP82–407–000, pursuant to Section 7(c) of the Natural Gas Act (NGA), all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Texas Gas states that it proposes to modify its existing Margaret Avenue Delivery Point to Indiana Gas by adding a six-inch orifice run in place of the existing four-inch by-pass and modifying the yard piping at Mile 140 on Texas Gas' Slaughters-Montezuma twelve-inch Line in Vigo County, Indiana. Texas Gas further states that it simultaneously proposes to abandon by sale to Indiana Gas the Terre Haute No. 3 Meter Station and a small section of the Terre Haute ten-inch Line in Vigo County, Indiana. Texas Gas also indicates that it proposes to install a six-inch delivery meter station for Indiana Gas at Texas Gas' Leesville Compressor Station on its North Bedford eight-inch Line. Texas Gas asserts that service to Indiana Gas will not be affected by the above abandonments. Texas Gas further asserts that there will be no significant impact on Texas Gas' peak day or annual deliveries due to the modification of the existing delivery point and that the addition of the new delivery point will not have any detriment to Texas Gas' other customers.

Any person or Commission Staff may, within 45 days of the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.214), a motion to intervene and pursuant to Section 157.205 of the regulations under the Natural Gas Act (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefor, the proposed activities shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 96–25571 Filed 10–4–96; 8:45 am]

BILLING CODE 6717–01–M

[Project No. 11566–001–ME]

Consolidated Hydro Maine, Inc.; Notice of Site Visit and Scoping Meeting Pursuant to the National Environmental Policy Act of 1969

October 1, 1996.

On August 19, 1996, the Federal Energy Regulatory Commission (Commission) issued a letter accepting the Consolidated Hydro Maine, Inc.'s application for initial license for the Damariscotta Mills Hydro Project, located on the Damariscotta River in Lincoln County, Maine.

The purpose of this notice is to: (1) Advise all parties as to the proposed scope of the staff's environmental analysis, including cumulative effects, and to seek additional information pertinent to this analysis; and (2) advise all parties of their opportunity for comment.

Scoping Process

The Commission's scoping objectives are to:

- Identify significant environmental issues;
- Determine the depth of analysis appropriate to each issue;
- Identify the resource issues not requiring detailed analysis; and
- Identify reasonable project alternatives.

The purpose of the scoping process is to identify significant issues related to the proposed action and to determine what issues should be addressed in the environmental document to be prepared pursuant to the National Environmental Policy Act of 1969 (NEPA). The document entitled ''Scoping Document I'' (SDI) will be circulated shortly to enable appropriate federal, state, and local resource agencies, developers, Indian tribes, nongovernmental organizations (NGO's), and other interested parties to effectively participate in and contribute to the scoping process. SDI provides a brief description of the proposed action, project alternatives, the geographic and temporal scope of a cumulative effects analysis, and a list of preliminary issues identified by staff.

Project Site Visit

The applicant and the Commission staff will conduct a site visit of the Damariscotta Mills Hydro Project on October 23, 1996, at 1 p.m. They will meet at the project powerhouse, located on Rt. 215 in Newcastle. All interested individuals, NGO's and agencies are invited to attend. All participants are responsible for their own transportation and should bring a hard hat. For more details, interested parties should contact Kevin Webb, the applicant contact, at (508) 681–1900 (ext. 1225), prior to the site visit date.

Scoping Meetings

The Commission staff will conduct two scoping meetings. All interested individuals, organizations, and agencies are invited to attend and assist the staff in identifying the scope of environmental issues that should be analyzed in the NEPA document.

The public scoping meeting will be held on October 22, 1996, from 6:00 p.m. to 10:00 p.m. at the Central High School, 194 Center St., Nobleboro, Maine 04555.

The agency scoping meeting will be held on October 23, 1996, from 9:00 a.m. to 12:00 p.m., at the Maine Dept. of Environmental Protection, Rm. LW–4, Ray Building-AMHI Complex, Hospital Street (Rt. 9), Augusta, ME 04333. For more details, interested parties should contact Dana Murch, Maine DEP, at (207) 287–3901, prior to the meeting date.

The Commission will decide, based on the application, and agency and public comments at the scoping session, whether licensing the Damariscotta Mills Project constitutes a major federal action significantly affecting the quality of the human environment. Irrespective of the Commission's determination to prepare an environmental assessment or an environmental impact statement for the Damariscotta Mills Project, the Commission staff will not hold

additional scoping meetings other than those scheduled, as listed above.

Objectives

At the scoping meetings, the Commission staff will: (1) Summarize the environmental issues tentatively identified for analysis in the NEPA document; (2) solicit from the meeting participants all available information, especially quantified data, on the resources at issue, and (3) encourage statements from experts and the public on issues that should be analyzed in the NEPA document. Individuals, organizations, and agencies with environmental expertise and concerns are encouraged to attend the meetings and to assist the staff in defining and clarifying the issues to be addressed.

Meeting Procedures

The meetings will be recorded by a stenographer and become a part of the formal record of the Commission proceeding on the Damariscotta Mills Project. Individuals presenting statements at the meetings will be asked to identify themselves for the record.

Concerned parties are encouraged to offer us verbal guidance during public meetings. Speaking time allowed for individuals will be determined before each meeting, based on the number of persons wishing to speak and the approximate amount of time available for the session, but all speakers will be provided at least 5 minutes to present their views.

All those attending the meeting are urged to refrain from making any communications concerning the merits of the application to any member of the Commission staff outside of the established process for developing the record as stated in the record of the proceeding.

Persons choosing not to speak but wishing to express an opinion, as well as speakers unable to summarize their positions within their allotted time, may submit written statements for inclusion in the public record no later than November 1, 1996.

All filings should contain an original and 8 copies. Failure to file on original and 8 copies may result in appropriate staff not receiving the benefit of your comments in a timely manner. See 18 CFR 4.34(h). In addition, commenters may submit a copy of their comments on a 3½-inch diskette formatted for MS–DOS based computers. In light of our ability to translate MS–DOS based materials, the text need only be submitted in the format and version that it was generated (i.e., MS Word, WordPerfect 5.1/5.2, ASCII, etc.). It is not necessary to reformat word processor generated text to ASCII. For Macintosh users, it would be helpful to save the documents in Macintosh word processor format and then write them to files on a diskette formatted for MS–DOS machines. All comments should be submitted to the Office of the Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, and should clearly show the following captions on the first page: Damariscotta Mills Hydro Project, FERC No. 11566.

Further, interested persons are reminded of the Commission's Rules of Practice and Procedures, requiring parties or interceders (as defined in 18 CFR 385.2010) to file documents on each person whose name is on the official service list for this proceeding. See 18 CFR 4.34(b).

The Commission staff will consider all written comments and may issue a Scoping Document II (SDII). SDII will include a revised list of issues, based on the scoping sessions.

For further information regarding the scoping process, please contact Rich Takacs, Federal Energy Regulatory Commission, Office of Hydropower Licensing, 888 First Street, NE, Washington, DC, 20426 at (202) 219–2840, or Ed Lee at (202) 219–2809.

Lois D. Cashell,

Secretary.

[FR Doc. 96–25570 Filed 10–4–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP96–720–000]

Natural Gas Pipeline Company of America; Notice of Intent To Prepare an Environmental Assessment for the Proposed Request for Comments on Environmental Issues

October 1, 1996.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the abandonment and construction of the facilities proposed in the Louisiana Line Expansion Project.[1] This EA will be used by the Commission in its decision-making process to determine whether an environmental impact statement is necessary and whether to approve the project.

Summary of the Proposed Project

Natural GAs Pipeline Company of America (NGPL) proposes to abandon the 3,800 horsepower (hp) compressor unit at Station No. 139 on its Permian Basin Line in Lea County, New Mexico and relocate it to Station No. 346 on its Louisiana Line in Cameron Parish, Louisiana. The compressor unit has not been used since 1993 and is no longer needed at Station No. 139. The compressor unit would be upgraded to a 4,500 hp rating and equipped with low emissions control technology. The additional horsepower would increase the capacity of the Louisiana Line by 63 MMcfd. NGPL No. 139. The general location of the project facilities are shown in appendix 1.[2]

NGPL also proposes to perform certain activities that it believes to be non-jurisdictional. These activities include the re-wheeling of three existing compressors at Station No. 346, Cameron Parish, Louisiana, to allow them to operate under the proposed operating conditions, and certain modifications to station piping at Station No. 342, Cameron Parish, Louisiana, in order to reduce pressure losses through the station when gas is being compressed for movement to the east.

Land Requirements for Construction

Only minor construction activities would be necessary to remove the compressor unit at Station No. 139 and install it at Station No. 346. All disturbance would occur within the existing compressor station sites. Station No. 346 is located on a 15 acre site. Approximately 2 acres of this site would be disturbed during the construction and installation of the compressor unit and associated structures. No additional roads would be required and the existing storage yards and parking facilities would be able to support contractor vehicles and storage areas as needed.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whether it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us to discover and address concerns the public may have about proposals. We call this ''scoping''. The main goal of the scoping process is to focus the analysis in the EA on the important

[1] Natural Gas Pipeline Company of America's application was filed with the Commission under Section 7 of the Natural Gas Act and Part 157 of the Commission's regulations.

[2] The appendices referenced in this notice are not being printed in the Federal Register. Copies are available from the Commission's Public Reference and Files Maintenance Branch, 888 First Street, N.E., Washington, D.C. 20426, or call (202) 208–1371. Copies of the appendices were sent to all those receiving this notice in the mail.

environmental issues. By this Notice of Intent, the Commission requests public comments on the scope of the issues it will address in the EA. All comments received are considered during the preparation of the EA. State and local government representatives are encouraged to notify their constituents of this proposed action and encourage them to comment on their areas of concern.

The EA will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings.

- Geology and soils.
- Water resources, fisheries, and wetlands.
- Vegetation and wildlife.
- Endangered and threatened species.
- Land use.
- Cultural resources.
- Air quality and noise.
- Public safety.

We will also evaluate possible alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Our independent analysis of the issues will be in the EA. Depending on the comments received during the scoping process, the EA may be published and mailed to Federal, state, and local agencies, public interest groups, interested individuals, affected landowners, newspapers, libraries, and the Commission's official service list for this proceeding. A comment period will be allotted for review if the EA is published. We will consider all comments on the EA before we recommend that the Commission approve or not approve the project.

Currently Identified Environmental Issues

We have already identified one issue that we think deserves attention based on a preliminary review of the proposed facilities and the environmental information provided by NGPL. Keep in mind that his is a preliminary list:

- Noise impact on the nearest residence located 1,320 feet to the north of Station No. 346.

The list of issues may be added to, subtracted from, or changed based on your comments and our analysis.

Public Participation

You can make a difference by sending a letter addressing your specific comments or concerns about the project. You should focus on the potential environmental effects of the proposal, alternatives to the proposal, and measures to avoid or lessen environmental impact. The more specific your comments, the more useful they will be. Please follow the instructions below to ensure that your comments are received and properly recorded:

- Address your letter to: Lois Cashell, Secretary, Federal Energy Regulatory Commission, 888 First St., N.E., Washington, D.C. 20426;
- Reference Docket No. CP96–720–000;
- Send a *copy* of your letter to: Ms. Mary Hertling, EA Project Manager, Federal Energy Regulatory Commission, 888 First St., N.E., PR–11.1, Washington, D.C. 20426; and
- Mail your comments so that they will be received in Washington, D.C. on or before November 7, 1996.

If you wish to receive a copy of the EA, you should request one from Ms. Hertling at the above address.

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an official party to the proceeding or become an ''intervenor''. Among other things, intervenors have the right to receive copies of case-related Commission documents and filings by other intervenors. Likewise, each intervenor must provide copies of its filings to all other parties. If you want to become an intervenor you must file a motion to intervene according to Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.214) (see appendix 2).

The date for filing timely motions to intervene in this proceeding has passed. Therefore, parties now seeking to file late interventions must show good cause, as required by section 385.214(b)(3), why this time limitations should be waived. Environmental issues have been viewed as good cause for late intervention. You do not need intervenor status to have your scoping comments considered.

Additional information about the proposed project is available from Ms. Mary Hertling, EA Project Manager, at (202) 208–0874.

Lois D. Cashell,

Secretary.

[FR Doc. 96–25573 Filed 10–4–96; 8:45 am]

BILLING CODE 6717–01–M

Western Area Power Administration

Notice of Availability of the Navajo Transmission Project Draft Environmental Impact Statement

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of availability and notice of public hearings.

SUMMARY: Western Area Power Administration's (Western) Colorado River Storage Project Customer Service Center (CRSP CSC) announces that the Navajo Transmission Project (NTP) Draft Environmental Impact Statement (draft EIS) is available for public review and comment. Western will hold public hearings to receive formal comments on the draft EIS according to the schedule below. The Din° Power Authority (DPA), an enterprise of the Navajo Nation, is proposing the construction and operation of a 500-kilovolt (kV) transmission line between northwestern New Mexico and southern Nevada, called the NTP. The draft EIS describes a range of alternatives considered and the potential environmental consequences and has been prepared in compliance with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*), the Council on Environmental Quality regulations for implementing NEPA (40 CFR Parts 1500–1508), and the DOE regulations for compliance with NEPA (10 CFR Part 1021). Western's CRSP CSC is the lead Federal agency to the NTP draft EIS.

DATES: Western will accept written and oral comments during the public review period. Written comments on the draft EIS should be sent to the Project Manager by December 6, 1996, of the EPA FR Notice at the following address: Mr. Tony Morton, EIS Manager, Western Area Power Administration, Colorado River Storage Project Customer Service Center, 257 East 200 South, Suite 475, P.O. Box 11606, Salt Lake City, Utah 84147–0606, telephone 801–524–5636.

Those wishing to make oral comments may do so at the scheduled public hearings. Speakers will be asked to register at the door prior to the beginning of the hearing. A court reporter will record the proceedings at each hearing. Interpreters for Navajo, Hopi or Hualapai Indians will be available at the appropriate sessions. Representatives will be responsible for recording comments and concerns of the public. Western will respond to all comments, both written and oral, in the final EIS.

The hearings will be held according to the following schedule. Western intends

to conduct open house information sessions for one hour prior to each hearing session to field questions and provide information to the public.

1. Monday, October 7, 10 a.m.—Sanostee Chapter
2. Monday, October 7, 10 a.m.—Coalmine Mesa Chapter
3. Monday, October 7, 6 p.m.—Beclabito Chapter
4. Tuesday, October 8, 10 a.m.—TeecNos Pos Chapter
5. Tuesday, October 8, 6 p.m.—Red Mesa Chapter
6. Thursday, October 10, 10 a.m.—Sweet Water Chapter
7. Thursday, October 10, 6 p.m.—Mexican Water Chapter
8. Monday, October 14, 10 a.m.—Nenahnezad Chapter
9. Monday, October 14, 2 p.m.—Whippoorwill Chapter
10. Monday, October 14, 6 p.m.—Farmington, NM, Civic Center, 200 West Arrington
11. Monday, October 14, 6 p.m.—TaChee/Blue Gap Chapter
12. Tuesday, October 15, 10 a.m.—San Juan Chapter
13. Tuesday, October 15, 10 a.m.—Pinon Chapter
14. Tuesday, October 15, 6 p.m.—Hogback Chapter
15. Tuesday, October 15, 6 p.m.—Hard Rock Chapter
16. Wednesday, October 16, 10 a.m.—Shiprock Chapter
17. Wednesday, October 16, 10 a.m.—Round Rock Chapter
18. Wednesday, October 16, 6 p.m.—Cudeii Chapter
19. Wednesday, October 16, 6 p.m.—Rock Point Chapter
20. Thursday, October 17, 10 a.m.—Red Valley Chapter
21. Thursday, October 17, 10 a.m.—Chilchinbeto Chapter
22. Thursday, October 17, 6 p.m.—Cove Chapter
23. Thursday, October 17, 6 p.m.—Shonto Chapter
24. Monday, October 21, 10 a.m.—St. Michaels Chapter
25. Monday, October 21, 10 a.m.—Cameron Chapter
26. Monday, October 21, 6 p.m.—Chinle Chapter
27. Monday, October 21, 6 p.m.—Bodaway Chapter
28. Tuesday, October 22, 10 a.m.—Tselani-Cottonwood Springs Chapter
29. Tuesday, October 22, 10 a.m.—Tuba City Chapter
30. Tuesday, October 22, 6 p.m.—Rough Rock Chapter
31. Tuesday, October 22, 6 p.m.—Tonalea Chapter
32. Wednesday, October 23, 10 a.m.—Many Farms Chapter
33. Wednesday, October 23, 10 a.m.—Inscription House Chapter
34. Wednesday, October 23, 6 p.m.—Lukachukai Chapter
35. Wednesday, October 23, 6 p.m.—Kaibeto Chapter
36. Thursday, October 24, 10 a.m.—Kayenta Chapter
37. Thursday, October 24, 10 a.m.—LeChee Chapter
38. Thursday, October 24, 6 p.m.—Dennehotso Chapter
39. Thursday, October 24, 6 p.m.—Coppermine Chapter
40. Tuesday, October 29, 10 a.m.—Flagstaff, AZ, Council Chambers
41. Tuesday, October 29, 6 p.m.—Hualapai Multi-Purpose Building, Hualapai Way and Diamond Creek, Peach Springs, AZ
42. Wednesday, October 30, 10 a.m.—Dolan Springs, AZ, Chamber Bldg, Pierce Ferry Road
43. Wednesday, October 30, 6 p.m.—Boulder City, NV, Super 8 Motel, 704 Nevada Hwy
44. Thursday, October 31, 6 p.m.—Hopi Cultural Center Motel, Second Mesa

Because there are so many hearings scheduled, there will be two hearings teams holding concurrent meetings throughout the project area. All chapter meetings will be held at the chapter houses on the Navajo Reservation, Arizona.

ADDRESSES: The CRSP CSC maintains a mailing list of those interested in the NTP EIS. Copies of the complete draft EIS, or a summary of the document (Introduction, Purpose and Need, and Description of the Alternatives) have been distributed to all persons and groups on the EIS mailing list, according to what each person/organization previously requested. A distribution has been made to various libraries and reading rooms in the project area. Copies of the draft EIS are available for public review at the Navajo chapter houses, the offices of the cooperating agencies, and other locations listed below:

Cooperating Agencies Offices

Bureau of Indian Affairs, Phoenix Area Office, One North First Street, Phoenix, AZ 85001.

Bureau of Indian Affairs, Navajo Area Office, 301 West Hill, Gallup, NM 87305.

Bureau of Indian Affairs, Truxton Canon Agency, 13067 East Highway 66, Valentine, AZ 86437.

Bureau of Indian Affairs, Hopi Agency, Main Street, Keams Canyon, AZ 86034.

Glen Canyon National Recreation Area, 691 Scenic Drive, Page, AZ 86040.

Lake Mead National Recreation Area, 601 Nevada Highway, Boulder City, NV 89005.

Bureau of Land Management, 1235 LaPlata Highway, Farmington, NM 87401.

Bureau of Land Management, 2475 Beverly Avenue, Kingman, AZ 86401.

Bureau of Land Management, 4765 Vegas Drive, Las Vegas, NV 89108.

Coconino National Forest, Peaks Ranger District, 5075 North Highway 89, Flagstaff, AZ 86004.

Kaibab National Forest, Tusayan Ranger District, Highway 64, Admin Site, Grand Canyon, AZ 86023.

Navajo Nation, Historic Preservation Office, Navajo Nation Inn Office Building, 48 West Highway 264, Window Rock, AZ 86515.

Hopi Tribe, Cultural Preservation Office, Main Street, Kykotsmovi, AZ 86039.

Hualapai Tribe, Office of Cultural Resources, 215 Diamond Creek Road, Peach Springs, AZ 86434.

Other Locations

Arizona State University, Hayden Library, Tempe, AZ 85287.

Flagstaff Public Library, 300 West Aspen Street, Flagstaff, AZ 86001.

Mohave County District Library, 3269 Burbank, Kingman, AZ 86401.

Mohave County Library, 1170 East Hancock Road, Bullhead City, AZ 86442.

Northern Arizona University, Cline Library, Flagstaff, AZ 86011.

Page Public Library, 697 Vista Avenue, Page, AZ 86040.

Phoenix Public Library, 1221 North Central Avenue, Phoenix, AZ 85004.

Seligman Public Library, 325 North Main Street, P.O. Box 623, Seligman, AZ 86337.

University of Arizona, Main Library, Tucson, AZ 85721.

Window Rock Library, Window Rock Administrative Offices, Dean Jackson's Education Center, Morgan Boulevard, Window Rock, AZ 86515.

Williams Public Library, 113 South First Street, Williams, AZ 86046.

Winslow Public Library, 420 West Gilmore Street, Winslow, AZ 86047.

Farmington Public Library, Reference Department, 100 West Broadway, Farmington, NM 87401.

University of New Mexico, Zimmerman Library, University Hill Northeast, Albuquerque, NM 87131.

Gallup Public Library, 115 West Hill Avenue, Gallup, NM 87301.

Boulder City Library, 539 California Avenue, Boulder City, NV 89005.

Clark County Library, 1401 East Flamingo Road, Las Vegas, NV 89109.

Henderson Library, 55 Water Street, Henderson, NV 89015.

Las Vegas Public Library, 833 North Las Vegas Boulevard, Las Vegas, NV 89101.

University of Nevada-Las Vegas, James Dickerson Library, P.O. Box 7001, Las Vegas, NV 89154–7001.

West Charleston Public Library, 6301 West Charleston Boulevard, Las Vegas, NV 89102.

Copies of the draft EIS and all supporting documents are also available for public review at Western's offices at:

Colorado River Storage Project, Customer Service Center, 257 East 200 South, Suite 475, Salt Lake City, UT 84147–0606.

Corporate Services Office, 1627 Cole Boulevard, Building 18, Golden, CO 80401.

This information is also available at the DOE Reading Room at the following address: U.S. Department of Energy, Forrestal Building, Reading Room 1E–190, 1000 Independence Avenue SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: For further information, to submit written comments, or to request a copy or summary of the draft EIS, please call or write the CRSP CRC at the address shown above.

For general information on DOE's NEPA review process, please contact: Carol M. Borgstrom, Director, Office of NEPA Policy and Assistance, EH–42, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–4600 or (800) 472–2756.

SUPPLEMENTARY INFORMATION: A surplus of electrical generation exists in the Four Corners region of the United States but there is insufficient capacity to transmit the power west, where it could be used to meet the needs of expanding load centers in Arizona, Nevada and California. The extra-high-voltage transmission system west of Four Corners consists of one 500-kV line and two 345-kV lines owned by Arizona Public Service (APS). There are restrictions on how much capacity each of the lines west of Four Corners may carry for reasons of safety and reliability. Since 1970, attempts to construct additional lines across the Navajo Reservation in northern Arizona have failed to gain approval of the Navajo Nation government.

The role of the Navajo Nation in the energy industry traditionally has been that of a passive resource owner. Nonrenewable resources from the Navajo Nation lands are exported to provide fuel for power for much of the western United States. The economy and self-sufficiency of the Navajo Nation depend heavily on the export of these resources. However, the businesses associated with the energy activities are typically non-Navajo. NTP is an opportunity for the Navajo Nation to own a majority of a transmission line that would be an integral part of a regional electrical transmission system, thereby establishing a role for the Navajo in the electric industry.

In 1992, DPA began studies to determine the feasibility of constructing and operating a Navajo majority-owned 500-kV transmission line that would deliver bulk electricity west from the Four Corners region of New Mexico. The project was viewed as an opportunity to provide a steady source of revenue for the Navajo Nation. The Navajo Nation is the second largest American Indian tribe in the United States and, according to the 1990 U.S. Census Bureau statistics, approximately 57 percent of families live below the poverty level.

As NTP is currently envisioned, revenue would be generated by leasing the capacity of the transmission line to regional utilities. Annual revenues over the life of the project would provide funds to allow the Navajo Nation to invest in other long-range productive business opportunities. The amount of revenue received by the DPA would depend on its final percent of ownership; right-of-way costs; lease agreements; construction, operation and maintenance costs; and availability of capacity. In addition, the development of NTP would provide short-term employment opportunities for American Indian groups during construction in a region having an unemployment rate of about 30 percent (on the Navajo Reservation). Skills and experience gained from construction jobs would be useful for future employment. After construction, it is anticipated that there may be limited opportunities for long-term employment in aspects of operation and maintenance of the transmission line. NTP is expected to contribute to an increase in the income and standard of living for the Navajo Nation.

Studies conducted by DPA and Western have shown that NTP would provide the needed transfer path for bulk electrical power and increase the electrical transfer level west of the Four Corners area. The additional capacity would support the existing system and prevent or reduce damages from outages, thereby enhancing the existing transmission grid and contributing to increased reliability, efficiency, and capability in the southwestern United States. By removing the existing transmission restrictions and/or interconnecting with other regional systems in the Four Corners area, Arizona, California, and Nevada utilities would be able to increase economical transfer of seasonal surpluses of electrical generation from resources in the Rocky Mountain and Four Corners areas and they would be able to support their peak load periods by importing power from existing hydro and coal-fired generation sources in the Rocky Mountain area. Such economic purchases reduce the use of more expensive generation.

More than 60 percent of Navajo Nation residences do not have electricity. Availability of electricity on the Navajo Reservation is critical to economic growth and infrastructure development of the Navajo Nation. NTP would allow Western an alternate path for firm-power deliveries across northern Arizona, thus reducing dependence and freeing capacity on Western's existing 230–kV transmission line for increased deliveries of electricity to the Kayenta and Long House Valley substations that currently provide service to the Navajo Tribal Utility Authority (NTUA). That would provide NTUA with more flexibility to plan additional distribution on the Navajo Reservation. Because of vast distances between available transmission and low-density populations of consumers on Navajo Nation lands, it is not economically feasible for NTUA alone to construct a high-voltage transmission line solely to accommodate the small number of business and residential consumers in the area. Also, NTP would allow access by the utility participants to the Western Systems Coordinating Council's (WSCC) southern 500–kV transmission grid, which covers the states of New Mexico, Arizona, and southern California. This would provide the opportunity for NTUA to buy less expensive power that may be available through regional and seasonal diversity, or due to the new Federal Energy Regulatory Commission's (FERC) transmission open access guidelines.

DPA approached Western in 1992 about participating in the proposed project. Western agreed to be the lead Federal agency for the project, in compliance with the National Environmental Policy Act, and agreed to take the responsibility for ensuring compliance with applicable regulations of other affected agencies. On May 26, 1993, Western announced in the Federal Register its intention to prepare an EIS on NTP. Western and DPA initiated extensive public involvement in the project, which has resulted in over 40 meetings with the public, and many meetings with a variety of state, tribal, county and local agencies and representatives. The effort was assisted by the cooperating agencies, consisting of representatives from units of the National Park Service; the U.S. Forest Service; the Bureau of Land

Management; and Bureau of Indian Affairs in Arizona, New Mexico, and Nevada; and three Tribes (Hopi, Hualapai, and Navajo). In addition, work on a Programmatic Agreement for the purposes of compliance with the National Historic Preservation Act resulted in contacts and comments from the Historic Preservation Officers of Nevada, New Mexico and Arizona, and 14 other area tribes.

This draft EIS was prepared to analyze and describe the environmental consequences of a range of alternatives. Western and DPA developed six alternatives for analysis in the draft EIS which are structured around the purpose and need. Four alternatives were removed from further analysis because they did not meet all of the requirements of the purpose and need, i.e., energy conservation and electric load management, new generation facilities, alternate transmission systems, and alternative transmission methods. The remaining two alternatives studied in depth in the EIS are identified as No Action and the Proposed Action. The Proposed Action included analysis of over 2,000 miles of routing alternatives. The draft EIS evaluates the potential impacts of the no action and proposed action alternatives on air quality, water resources (water quality and floodplain management), earth resources (geology, mineral resources, seismicity and faults, and soils and erosion potential), biological resources, paleontological resources, land use (linear features; jurisdictions; existing and future land use; and parks, preservation, and recreation), socioeconomic resources, visual resources, and cultural resources. Environmentally preferred options have been identified, however, no preferred construction route is identified in the draft EIS. A decision on the proposed action will be made after considering comments on the draft EIS. A final routing alternative will be recommended in the final EIS.

Issued at Golden, Colorado, September 23, 1996.

J. M. Shafer,

Administrator.

[FR Doc. 96–25613 Filed 10–4–96; 8:45 am]

BILLING CODE 6450–01–P

[Rate Order No. WAPA–73]

Colorado River Storage—Confirming and Approving an Extension of the Firm Transmission Service Rate

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of a rate order.

SUMMARY: The purpose of Rate Order No. WAPA–73 is to extend Rate Schedule SP–FT4 until September 30, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. David Sabo, CRSP Manager, CRSP Customer Service Center, Western Area Power Administration, P.O. Box 11606, Salt Lake City, UT 84147–0606, (801) 524–5493.

SUPPLEMENTARY INFORMATION: By Amendment No. 3 to Delegation Order No. 0204–108, published November 10, 1993 (58 FR 59716), the Secretary of Energy redelegated (1) the authority to develop long-term power and transmission rates on a nonexclusive basis to the Administrator of Western; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary; and (3) the authority to confirm, approve, and place into effect on a final basis, to remand, or to disapprove such rates to the Federal Energy Regulatory Commission (FERC). Existing Department of Energy procedures for public participation in power rate adjustments (10 CFR Part 903) became effective on September 18, 1985 (50 FR 37835).

Pursuant to Delegation Order No. 0204–108, Western's Colorado River Storage Project (CRSP) firm transmission rate case was submitted to the Federal Energy Regulatory Commission for confirmation and approval on August 13, 1992. On February 18, 1993, in Docket Nos. EF92–5172–000 and EF92–5172–001, at 62 FERC ¶ 61,159, FERC issued an order confirming, approving, and placing in effect on a final basis Rate Schedule SP–FT4 for firm transmission service over the CRSP transmission system. The rate was approved for the 4-year period beginning October 1, 1992, and ending September 30, 1996.

Western proposes to extend the existing CRSP firm transmission rate until September 30, 1997. During the last firm-power rate adjustment for the Salt Lake Integrated Projects, placed into effect on December 1, 1994 (SLIP-F5), the CRSP firm transmission rate was examined. It was determined that the existing firm transmission rate was still adequate to meet revenue requirements. The costs associated with the Salt Lake City Integrated Projects' firm power rate increase were offset in the CRSP firm transmission rate study by an increase in transmission revenues not associated with the firm transmission rate.

Issued in Washington, D.C., September 27, 1996.

Charles B. Curtis,

Deputy Secretary.

Order Confirming and Approving an Extension of the Colorado River Storage Project Firm Transmission Rate

October 1, 1996.

These power rates were established pursuant to Section 302(a) of the Department of Energy (DOE) Organization Act, 42 U.S.C. 7152(a), through which the power marketing functions of the Secretary of the Interior and the Bureau of Reclamation (Reclamation) under the Reclamation Act of 1902, ch. 1093, 32 Stat. 388, as amended and supplemented by subsequent enactments, particularly section 9(c) of the Reclamation Project Act of 1939, 43 U.S.C. 485h(c), and other acts specifically applicable to the project system involved, were transferred to and vested in the Secretary of Energy (Secretary).

By Amendment No. 3 to Delegation Order No. 0204–108, published November 10, 1993 (58 FR 59716), the Secretary redelegated (1) the authority to develop long-term power and transmission rates on a nonexclusive basis to the Administrator of the Western Area Power Administration (Western); (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary; and (3) the authority to confirm, approve, and place into effect on a final basis, to remand, or to disapprove such rates to the Federal Energy Regulatory Commission (FERC). Existing DOE procedures for public participation in power rate adjustments (10 CFR Part 903) became effective on September 18, 1985 (50 FR 37835). This rate extension is issued pursuant to the Delegation Order and the rate extension procedures in 10 CFR Part 903.

Background

Pursuant to Delegation Order No. 0204–108, in the order issued February 18, 1993, at 62 FERC ¶ 61,159, in Docket Nos. EF92–5172–000 and EF92–5172–001, the FERC confirmed, approved, and placed in effect on a final basis Rate Schedule SP–FT4 for firm transmission service over the Colorado River Storage Project (CRSP) transmission system. The rate was approved for the period from October 1, 1992, through September 30, 1996.

Discussion

On September 30, 1996, Western's CRSP firm transmission rate will expire. This makes it necessary to extend the

current Rate Schedule SP–FT4 to comply with 10 CFR 903.23.

Western proposes to extend the existing CRSP transmission rate until September 30, 1997.

During the last firm-power rate adjustment for the Salt Lake Integrated Projects, placed into effect on December 1, 1994 (SLIP–F5), the CRSP firm transmission rate was also examined for possible adjustment. It was determined that the existing firm transmission rate was adequate to meet revenue requirements. The CRSP costs associated with the Salt Lake City Integrated Projects' firm power rate increase were offset in the CRSP firm transmission rate study by an increase in transmission revenues not associated with the firm transmission rate.

Order

In view of the foregoing and pursuant to the authority delegated to me by the Secretary, I hereby confirm and approve for a period effective October 1, 1996, until September 30, 1997, the existing Rate Schedule SP–FT4 for firm transmission service over the Colorado River Storage Project transmission system.

Issued in Washington, D.C., September 27, 1996.

Charles B. Curtis,

Deputy Secretary.

[FR Doc. 96–25612 Filed 10–4–96; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5630–7]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that EPA is planning to submit the following continuing Information Collection Request (ICR) to the Office of Management and Budget (OMB): Contractor Cumulative Claim and Reconciliation, OMB Control No. 2030–0016. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before December 6, 1996.

ADDRESSES: Office of Acquisition Management (3802F), 401 M. Street S.W., Washington, D.C. 20460. Attention: Edward N. Chambers.

FOR FURTHER INFORMATION CONTACT: Edward N. Chambers; (202)260–6028, FAX: (202) 260–1203; CHAMBERS.EDWARD@A1@MAIL

SUPPLEMENTARY INFORMATION:

Affected entities: Entities potentially affected by this action are contractors with cost reimbursement contracts.

Title: Contractor Cumulative Claim and Reconciliation, OMB Control No. 2030–0016, expiration date 2–28–97.

Abstract: At the conclusion of cost reimbursable contracts, contractors will report the cumulative costs incurred, including direct labor, materials, supplies, equipment, other direct costs, subcontracting, consultant fees, indirect costs and fixed fee. Contractors will report this information one time on EPA Form 1900–10. EPA will use this information to reconcile the contractor's costs. Establishment of the final costs and fixed fee is necessary for closeout of the contract.

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.

The EPA would like to solicit comments to:

(i) 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;

(ii) 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;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) 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 responses.

Burden Statement: The estimated annual public reporting and recordkeeping burden for this collection is 42.9 hours. This represents an average of 40 minutes for each of the 65 cost reimbursable contracts estimated to be physically complete per fiscal year. The total number of responses is estimated at 65 (1 reponse per contract×65 contracts). The annual cost of this collection is estimated at $1,133.60 (17.44 per contract x 65 contracts). 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; to develop, to acquire, to install, and to utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to adjust the existing methods to comply with any previously applicable instructions and requirements; to train personnel to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information.

Dated: September 23, 1996.

Edward J. Murphy,

Chief, Procurement Policy Branch.

[FR Doc. 96–25656 Filed 10–4–96; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5631–1, OMB No. 2060–0145; EPA No. 1150.04]

Agency Information Collection Activities Under OMB Review; VOC Emission Standards for the Polymer Manufacturing Industry

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3507 (a)(1)(D), *et seq.*), this notice announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: VOC Emission Standards for the Polymer Manufacturing Industry, Subpart DDD, OMB NO. 2060–0145; EPA NO. 1150.04, expiring November 30, 1996. The ICR describes the nature of the information collection and the expected burdens and costs.

DATES: Comments must be submitted on or before November 6, 1996.

FOR FURTHER INFORMATION OR A COPY CALL: Sandy Farmer at EPA, (202) 260–2740, and refer to EPA ICR No. 1150.04.

SUPPLEMENTARY INFORMATION:

Title: Volatile Organic Compound (VOC) Emissions Standards for the Polymer Manufacturing Industry, Subpart DDD, OMB Control No. 2060–

0145; EPA ICR No. 1150.04. expiring November 30, 1996. This is a request for an extension of a currently approved collection.

Abstract: The Agency uses the information required by 40 CFR part 60, Subpart DDD to identify sources subject to the standards and to ensure that the best demonstrated technology is being properly applied. The standards require periodic recordkeeping to document process information relating to the sources' ability to meet the requirements of the standard and to note the operation conditions under which compliance was achieved.

Owners or operators of the affected facilities described must make the following one-time-only reports: notification of the date of construction or reconstruction; notification of the anticipated and actual dates of startup; notification of any physical or operational change to an existing facility which may increase the regulated pollutant emission rate; notification of the date of the initial performance test; and the results of the initial performance test. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports and records are required, in general, of all sources subject to New Source Performance Standards.

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. The Federal Register Notice with a 60-day comment period soliciting comments on this collection of information was published on 06/11/96 (FR 14681).

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 51.8 hours per response. This estimate 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.

Affected Entities: Polymer manufacturers.

Estimated No. of Respondents: 90.

Estimated Total Annual Burden on Respondents: 12,425 hours.

Frequency of Collection: Semiannual.

Send comments on the Agency's need for the information in this collection, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the following addresses. Please refer to EPA ICR Number 1150.04 and OMB Control Number 2060–0145 in any correspondence.

Ms. Sandy Farmer, U.S. Environmental Protection Agency, OPPE Regulatory Information Division (2137), 401 M Street, SW, Washington, DC 20460.

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

Dated: September 30, 1996.

Joseph Retzer,

Director, Regulatory Information Division.

[FR Doc. 96–25658 Filed 10–4–96; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5631–8]

Underground Injection Control Program Nonhazardous Waste Disposal Injection Restriction Petition for Exemption—Class I Nonhazardous Waste Injection Has Been Granted to Abbott Laboratories, Wichita, Kansas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final decision.

SUMMARY: Notice is hereby given that an exemption to the land disposal restrictions under the 1984 Hazardous and Solid Waste Amendments to the Resource Conservation and Recovery Act has been granted to Abbott Laboratories for their Class I Nonhazardous Waste injection well located in Wichita, Kansas. This final decision allows the underground injection by Abbott Laboratories of the specific restricted waste, identified in the petition, into the Class I waste injection well at the Wichita, Kansas, facility, for as long as the basis for granting an approval of the petition remains valid, under provisions of Title 40 Code of Federal Regulations Part 124. As required by Title 40 Code of Federal Regulations Part 148, the company has adequately demonstrated to the satisfaction of the United States Environmental Protection Agency by petition and supporting documentation that, to a reasonable degree of certainty, there will be no migration of the restricted, greater than 10 percent high total organic carbon (TOC) constituents from the injection zone. A public notice was published on July 22, 1996, that requested written comments be submitted by August 22, 1996. No comments were received during the comment period. This decision constitutes final Agency action. There is no administrative appeal process that can be applied to a final petition decision.

EFFECTIVE DATE: This action is effective as of September 12, 1996.

ADDRESSES: Copies of the petition and all the pertinent information relating thereto, including the Agency's response to comments, are on file at the following location: Environmental Protection Agency, Region 7, Water, Wetlands and Pesticides Division, Drinking Water/Groundwater Management Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101.

FOR FURTHER INFORMATION CONTACT: Robert L. Morby, Chief, Drinking Water/Groundwater Management Branch, Environmental Protection Agency, Region 7. Telephone (913) 551–7682.

Dated: September 12, 1996.

Dennis Grams,

Regional Administrator.

[FR Doc. 96–25657 Filed 10–4–96; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5631–9]

Agency Information Collection Activities Under OMB Review

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: This notice announces the Office of Management and Budget's (OMB) responses to Agency clearance requests, in compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). 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.

FOR FURTHER INFORMATION CONTACT: Sandy Farmer (202) 260–2740, please refer to the appropriate EPA Information Collection Request (ICR) Number.

SUPPLEMENTARY INFORMATION:

OMB Responses to Agency Clearance Requests

OMB Approvals

EPA ICR No. 1541.95; For Benzene Waste Operations—Subpart FF; was approved 09/25/96; OMB No. 2060–0183; expires 09/30/99.

EPA ICR No. 1786.01; Auto Refinishing Industry Solvent-Use Survey (ARSUS); was approved 09/25/96; OMB No. 2080–0055; expires 09/30/99.

EPA ICR No. 0011.08; Selective Enforcement Auditing and Recordkeeping Requirements for On-Highway Heavy-Duty Engines, Nonroad Large Compression Ignition Engines, and On-Highway Light-Duty Vehicles and Light-Duty Trucks; was approved 08/30/96; OMB No. 2060–0064; expires 08/31/99.

EPA ICR No. 1763.01; In-Use Credit Program for New Marine Engines; was approved 09/25/96; OMB No. 2060–0325; expires 09/30/99.

EPA ICR No. 0116.05; Emission Control System Performance Warranty Regulations and Voluntary Aftermarket Part Certification Program; was approved 08/30/96; OMB No. 2060–0060; expires 08/31/99.

EPA ICR No. 1773.01; Reporting and Recordkeeping Requirements for National Emissions Standards for Hazardous Air Pollutants from Hazardous Waste Combustors; was approved 09/25/96; OMB No. 2060–0349; expires 09/30/99.

EPA ICR No. 1643.02; Extension for Application Requirements for the Approval and Delegation of Federal Air Toxics Programs to State and Local Agencies; was approved 09/18/96; OMB No. 2060–0264; expires 09/30/99.

EPA ICR No. 0111.08; National Emission Standards for Asbestos; was approved 09/16/96; OMB No. 2060–0101; expires 09/30/99.

EPA ICR No. 1055.05; NSPS for Kraft Pulp Mills—Subpart BB Recordkeeping and Reporting; was approved 09/09/96; OMB No. 2060–0021; expires 09/30/99.

EPA ICR No. 0658.06; NSPS for Pressure Sensitive Tape and Label Surface Coating—Subpart RR; was approved 09/18/96; OMB No. 2060–0004; expires 09/30/99.

EPA ICR No. 1052.05; NSPS for Fossil-Fuel-Fired Steam Generating Units—Subpart D; was approved 09/09/96; OMB No. 2060–0026; expires 09/30/99.

EPA ICR No. 1139.05; TSCA Section 4 Test Rules, Consent Orders and Test Rule Exemptions; was approved 09/06/96; OMB No. 2070–0033; expires 09/30/99.

EPA ICR No. 1717.02; National Emission Standards for Hazardous Air Pollutants (NESHAP) for Off-Site Waste and Recovery Operations—Subpart DD; was approved 09/18/96; OMB No. 2060–0313; expires 09/30/99.

Correction

EPA ICR No. 1053.05; NSPS for Electric Utility Steam Generating Units—Subpart Da; OMB No. 2060–0023; expiration date is 09/30/99 instead of 09/30/96.

Dated: October 2, 1996.

Joseph Retzer,

Director, Regulatory Information Division.

[FR Doc. 96–25651 Filed 10–4–96; 8:45 am]

BILLING CODE 6560–50–M

[FRL 5631–5]

Proposed Settlement Under the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as Amended (''CERCLA''), In the Matter of the Prestolite Battery Superfund Site, Knox County, IN

AGENCY: Environmental Protection Agency.

ACTION: Notice of a proposed administrative settlement and request for public comment.

SUMMARY: The Environmental Protection Agency (''EPA'') is hereby giving notice that it proposes to enter into an administrative prospective purchaser settlement relating to the Prestolite Battery Superfund Site located in Vincennes, Knox County, Indiana. The proposed settlement is with Rex and Rita Alton, d/b/a Rex Alton & Companies (''Alton''), and will resolve their prospective liability, pursuant to Sections 106 and 107(a) of CERCLA, for injunctive relief and for past response costs incurred in connection with the Prestolite Battery Site. This notice is an invitation to file written comments on the proposed administrative settlement.

DATES: Comments must be provided on or before November 6, 1996.

ADDRESSES: Comments should be addressed to Elizabeth Murphy, Office of Regional Counsel, Mail Code C–29A, U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604–3590, and should refer to: In the Matter of Prestolite Battery Site.

FOR FURTHER INFORMATION CONTACT: Elizabeth Murphy, Office of Regional Counsel, Mail Code C–29A, U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604–3590, 312/886–0748.

SUPPLEMENTARY INFORMATION: The Prestolite Battery site (''Site'') is an inactive lead-acid battery manufacturing facility located in Knox County, Indiana. The facility occupies approximately 18 acres on U.S. Highway 41 northeast of the city of Vincennes. Lead-acid batteries were manufactured at the Site from 1945 to 1985, at which time the current owner, Allied-Signal, Inc., ceased operations at the plant. As a result of the manufacturing process, the soil and atmosphere surrounding the Site became contaminated with lead and polychlorinated biphenyls and the groundwater underlying the Site became contaminated with Site-related chlorinated solvents.

The Site was placed on the National Priorities List in 1989. Pursuant to an administrative order on consent, Allied-Signal, Inc. removed lead-contaminated soil and debris from the Site. Additionally, the buildings and on- and off-Site sewers have been decontaminated for lead, and asbestos has been removed from some areas of the buildings. On August 23, 1994, U.S. EPA issued a Record of Decision which calls for long-term monitoring of the groundwater, surface water and sediments; provision of municipal water to a nearby resident; and abandonment of one unused well. Implementation of this remedy is currently the subject of negotiations between EPA and Allied-Signal, Inc.

On March 29, 1995, EPA perfected a CERCLA lien against the Site property to secure the payment of its response costs. This lien has interfered with the closing of a transfer of ownership of the site property from Allied-Signal, Inc. to Alton. Under the terms of the proposed agreement, EPA has agreed to lift the lien on the property and is providing a covenant not to sue Alton for any existing contamination at the Site in exchange for Alton's placement of the purchase price into an interest-bearing escrow account pending final resolution of the case between EPA and Allied-Signal, Inc., at which time the proceeds will be disbursed accordingly. Additionally, the agreement provides Alton will demolish all of the existing buildings and other structures on the Site which currently are in a poor and unsightly state of repair. Alton intends to commercially develop the Site and anticipates that in so doing, approximately 150 new employment opportunities will be created.

The Environmental Protection Agency will receive written comments relating to this agreement for thirty days from the date of publication of this notice.

Authority: The Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, 42 U.S.C. 9601 *et seq.*

Richard C. Karl,

Acting Director, Superfund Division.

[FR Doc. 96–25652 Filed 10–4–96; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5631–7]

Notice of Proposed Assessment of Clean Water Act Class II Administrative Penalty to Circuit Logic, Inc. and Opportunity To Comment

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed administrative penalty assessment and opportunity to comment.

SUMMARY: EPA is providing notice of proposed administrative penalty assessment for alleged violations of the Clean Water Act. EPA is also providing notice of opportunity to comment on the proposed assessment.

Under 33 U.S.C. 1319(g), EPA is authorized to issue orders assessing civil penalties for various violations of the Act. EPA may issue these orders after the commencement of either a Class I or Class II penalty proceeding. EPA provides public notice of the proposed assessments pursuant to 33 U.S.C. 1319(g)(4)(a).

Class II proceedings are conducted under EPA's Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation and Suspension of Permits, 40 CFR Part 22. The procedures through which the public may submit written comment on a proposed Class II order or participate in a Class II proceeding, and the Procedures by which a Respondent may request a hearing, are set forth in the Consolidated Rules. The deadline for submitting public comment on a proposed Class II order is thirty days after publication of this notice.

On the date identified below, EPA commenced the following Class II proceeding for the assessment of penalties:

In the Matter of Circuit Logic, Inc., 311 Enterprise Street, Escondido, California; EPA Docket No. CWA–IX–FY96–17; filed on September 30, 1996, with Mr. Steven Armsey, Regional Hearing Clerk, U.S. EPA, Region 9, 75 Hawthorne Street, San Francisco, California 94105, (415) 744–1389; proposed penalty of up to $125,000 for failure to comply with the categorical pretreatment standards and requirements for new source metal finishers (40 CFR 433).

FOR FURTHER INFORMATION: Persons wishing to receive a copy of EPA's Consolidated Rules, review of the complaint or other documents filed in this proceeding, comment upon a proposed assessment, or otherwise participate in the proceeding should contact the Regional Hearing Clerk identified above. The administrative record for this proceeding is located in the EPA Regional Office identified above, and the file will be open for public inspection during normal business hours. All information submitted by the respondent is available as part of the administrative record, subject to provisions of law restricting public disclosure of confidential information. In order to provide opportunity for public comment, EPA will issue no final order assessing a penalty in these proceedings prior to thirty (30) days after the date of publication of this notice.

Dated: September 30, 1996.

John Ong,

Acting Director, Water Management Division.

[FR Doc. 96–25655 Filed 10–4–96; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[WRC–97]

Preparation For The 1997 World Radiocommunication Conference

AGENCIES: Federal Communications Commission and National Telecommunications and Information Administration.

ACTION: Notice; announcement of draft preliminary proposals to WRC–97.

SUMMARY: The FCC and NTIA have released Joint Draft Preliminary Proposals for WRC–97. The public is provided a 30-day period, from the date of the release of the notice, to provide comment on the draft proposals. Copies of the draft proposals are available for inspection and photocopying at the FCC's International Reference Center, 2000 M Street, N.W., Room 102, Washington, D.C., and on-line at http://www.fcc.gov/ib/wrc97/. Final U.S. proposals will be determined by the Department of State based on the recommendations of the FCC and NTIA.

DATES: Comments must be submitted on or before October 24, 1996.

ADDRESSES: Office of the Secretary, Federal Communications Commission, 1919 M Street, N.W., Washington, D.C. 20554; Director, Office of Spectrum Plans and Policies, National Telecommunications and Information Administration, Department of Commerce, Room 4099, Washington, D.C. 20230.

FOR FURTHER INFORMATION CONTACT: Crystal Foster, FCC, 202–418–0749 and William T. Hatch, NTIA, at 202–482–1138.

SUPPLEMENTARY INFORMATION: The FCC's WRC–97 Advisory Committee and NTIA, through the Interdepartment Radio Advisory Committee, announced on September 24, 1996, their approval of an initial set of draft preliminary proposals for WRC–97. In accordance with the streamlined procedures developed to improve the United States conference preparation process, the agencies are providing the public with this early opportunity to review and comment on draft proposals before further consideration. Final U.S. proposals will be determined by the Department of State based on the recommendations of the FCC and NTIA.

The joint preliminary draft proposals seek to:

(1) Continue simplification of the international Radio Regulations;

(2) Improve sharing criteria for worldwide Mobile Satellite-Service (MSS) allocations below 1 GHz;

(3) Ensure availability of 1610–1626.5 MHz and 2483.5–2500 MHz for non-geostationary (NGSO) MSS systems;

(4) To harmonize MSS 2 GHz allocations;

(5) Extend bands designated for sharing between NGSO MSS and GSO Fixed-Satellite Service systems to 19.3–19.7 GHz and 29.1–29.5 GHz;

(6) Upgrade the space research service allocation at 410–420 GHz for extra-vehicular activities by astronauts;

(7) Upgrade the allocation for Earth Exploration-Satellite service (EES) (space-to-Earth) at 25.5–27 GHz;

(8) Establish a common worldwide primary allocation for the EES at 8025–8400 MHz; and

(9) Maintain the current allocation for passive space borne sensors at 10.6–10.68 GHz and 10.68–10.7 GHz.

Members of the public are invited to provide to the FCC and NTIA comments on the joint preliminary draft proposals. Commenters should send an original plus one copy of their comment to the Office of the Secretary, Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554. Comments should clearly note ''Reference No. ISP–96–005'' to ensure proper routing and should refer to specific proposals by their Joint Preliminary Draft Proposal number. Copies of the comments should also be submitted to the Director, Office of Spectrum Plans and Policies, National Telecommunications and Information

Administration, Department of Commerce, Room 4099, Washington, DC 20230. Parties preferring to e-mail their comments should address their comments to WRC97@fcc.gov and WRC97@ntia.doc.gov and they should reference ''First Draft Proposals'' in the subject line.

The deadline for comments on this first set of joint preliminary draft proposals is October 24, 1996. Timely comments will be considered by the FCC WRC–97 Advisory Committee and will be made available for public inspection at the FCC's International Reference Center, 2000 M Street, NW., Room 102, Washington, DC, 202–418–1492. Copies of the documents can be purchased through the FCC's duplication contractor, ITS, Inc., 202–857–3800.

Further information about the FCC WRC–97 Advisory Committee, including its schedule of meetings, is available on the Internet at http://www.fcc.gov/ib/wrc97/. Meetings of the Advisory Committee and its Informal Working Groups are open to the public.

Federal Communications Commission.

Shirley S. Suggs,

Chief, Publications Branch.

[FR Doc. 96–25135 Filed 10–4–96; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than October 21, 1996.

A. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Lynn P. Carr, Wyoming, Michigan; to retain a total of 14.81 percent of the voting shares of Lakeview Financial Corporation, Lakeview, Michigan, and thereby indirectly retain Bank of Lakeview, Lakeview, Michigan.

Board of Governors of the Federal Reserve System, October 1, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–25582 Filed 10-04-96; 8:45 am]

BILLING CODE 6210-01-F

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. Once the application has been accepted for processing, it will also 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, including whether the acquisition of the nonbanking company can ''reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices'' (12 U.S.C. 1843). Any request for a hearing must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

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 October 31, 1996.

A. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. First Union Corporation, Charlotte, North Carolina; to acquire 100 percent of the voting shares of Boca Raton First National Bank, Boca Raton, Florida.

B. Federal Reserve Bank of Minneapolis (Karen L. Grandstrand, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. First State Bancorp, Inc., La Crosse, Wisconsin; to acquire 100 percent of the voting shares of First Bancorporation, Inc., Sparta, Wisconsin, and thereby indirectly acquire First Bank of Sparta, Sparta, Wisconsin.

Board of Governors of the Federal Reserve System, October 1, 1996.

Jennifer J. Johnson

Deputy Secretary of the Board

[FR Doc. 96–25583 Filed 10-04-96; 8:45 am]

BILLING CODE 6210-01-F

Federal Open Market Committee; Domestic Policy Directive of August 20, 1996.

In accordance with § 271.5 of its rules regarding availability of information (12 CFR part 271), there is set forth below the domestic policy directive issued by the Federal Open Market Committee at its meeting held on August 20, 1996.[1] The directive was issued to the Federal Reserve Bank of New York as follows:

The information reviewed at this meeting suggests that growth in economic activity recently has moderated somewhat. Private nonfarm payroll employment grew less rapidly in July, the average workweek fell sharply, and the civilian unemployment rate edged up to 5.4 percent. Industrial production increased slightly in July after three months of strong gains. Real consumer spending weakened somewhat on balance over June and July following several months of robust growth. Housing starts fell somewhat further in July. Growth in spending on business equipment and nonresidential structures has slowed after a very rapid

[1] Copies of the Minutes of the Federal Open Market Committee meeting of August 20, 1996, which include the domestic policy directive issued at that meeting, are available upon request to the Board of Governors of the Federal Reserve System, Washington, D.C. 20551. The minutes are published in the Federal Reserve Bulletin and in the Board's annual report.

expansion earlier in the year. The nominal deficit on U.S. trade in goods and services widened in the second quarter from its rate in the first quarter. Increases in labor compensation have been somewhat larger this year, but consumer price inflation, adjusted for food and energy prices, has remained on a fairly steady trend.

Most short-term market interest rates have declined slightly while intermediate- and long-term rates have fallen somewhat more since the Committee meeting on July 2-3, 1996. In foreign exchange markets, the trade-weighted value of the dollar in terms of the other G-10 currencies has depreciated slightly over the intermeeting period.

Growth of M2 and M3 moderated in July. For the year through July, both aggregates are estimated to have grown at rates somewhat below the upper bounds of their respective ranges for the year. Expansion in total domestic nonfinancial debt has been moderate on balance over recent months and has remained in the middle portion of its range.

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. In furtherance of these objectives, the Committee at its meeting in July reaffirmed the ranges it had established in January for growth of M2 and M3 of 1 to 5 percent and 2 to 6 percent respectively, measured from the fourth quarter of 1995 to the fourth quarter of 1996. The monitoring range for growth of total domestic nonfinancial debt was maintained at 3 to 7 percent for the year. For 1997 the Committee agreed on a tentative basis to set the same ranges as in 1996 for growth of the monetary aggregages and debt, measured from the fourth quarter of 1996 to the fourth quarter of 1997. The behavior of the monetary aggregates will continue to be evaluated in the light of progress toward price level stability, movements in their velocities, and developments in the economy and financial markets.

In the implementation of policy for the immediate future, the Committee seeks to maintain the existing degree of pressure on reserve positions. In the context of the Committee's long-run objectives for price stability and sustainable economic growth, and giving careful consideration to economic, financial, and monetary developments, somewhat greater reserve restraint would or slightly lesser reserve restraint might be acceptable in the intermeeting period. The contemplated reserve conditions are expected to be consistent with moderate growth in M2 and M3 over coming months.

By order of the Federal Open Market Committee, September 30, 1996.

Donald L. Kohn,

Secretary, Federal Open Market Committee.

[FR Doc. 96–25581 Filed 10–4–96; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96F–0348]

MacMillan Bloedel, Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that MacMillan Bloedel, Ltd., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of ethylene glycol as a pulp bleaching agent for paper and paperboard intended for use in contact with food.

DATES: Written comments on the petitioner's environmental assessment by November 6, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3095.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 6B4520) has been filed by MacMillan Bloedel, Ltd., c/o Camplong & Associates, Inc., P.O. Box 238, Schomberg, ON L0G 1T0, Canada. The petition proposes to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of ethylene glycol as a pulp bleaching agent for paper and paperboard intended for use in contact with food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before November 6, 1996, submit to the Dockets Management Branch (address above) written comments. 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 office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: September 18, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–25548 Filed 10–04–96; 8:45 am]

BILLING CODE 4160–01–F

Product and Establishment License Applications, Refusal to File; Meeting of Oversight Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting of its standing oversight committee in the Center for Biologics Evaluation and Research (CBER) that conducts a periodic review of CBER's use of its refusal to file (RTF) practices on product license applications (PLA's) and establishment license applications (ELA's). CBER's RTF oversight committee examines all RTF decisions which occurred during the previous quarter to assess consistency across CBER offices and divisions in RTF decisions.

DATES: The meeting will be held on October 8, 1996.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM–5), Food

and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0379.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 15, 1995 (60 FR 25920), FDA announced the establishment and first meeting of CBER's standing oversight committee. As explained in the notice, the importance to the public health of getting new biological products on the market as efficiently as possible has made improving the biological product evaluation process an FDA priority. CBER's managed review process focuses on specific milestones or intermediate goals to ensure that a quality review is conducted within a specified time period. CBER's RTF oversight committee meetings continue CBER's effort to promote the timely, efficient, and consistent review of PLA's and ELA's.

FDA regulations on filing PLA's and ELA's are found in 21 CFR 601.2 and 601.3. A sponsor who receives an RTF notification may request an informal conference with CBER, and thereafter may ask that the application be filed over protest, similar to the procedure for drugs described under 21 CFR 314.101(a)(3).

CBER's standing RTF oversight committee consists of senior CBER officials, a senior official from the FDA's Center for Drug Evaluation and Research, and FDA's Chief Mediator and Ombudsman. Meetings will ordinarily be held once a quarter to review all of the RTF decisions. The purpose of such a review is to assess the consistency within CBER in rendering RTF decisions.

Because the committee's deliberations will deal with confidential commercial information, all meetings will be closed to the public. The committee's deliberations will be reported in the minutes of the meeting. Although those minutes will not be publicly available because they will contain confidential commercial information, summaries of the committee's deliberations, with all confidential commercial information omitted, may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. If, following the committee's review, an RTF decision changes, the appropriate division within CBER will notify the sponsor.

Dated: September 26, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–25600 Filed 10–04–96; 8:45 am]

BILLING CODE 4160–01–F

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies, and Laboratories That Have Withdrawn From the Program

AGENCY: Substance Abuse and Mental Health Services Administration, HHS (Formerly: National Institute on Drug Abuse, ADAMHA, HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be identified as such at the end of the current list of certified laboratories, and will be omitted from the monthly listing thereafter.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh, Division of Workplace Programs, Room 13A–54, 5600 Fishers Lane, Rockville, Maryland 20857; Tel.: (301) 443–6014.

SUPPLEMENTARY INFORMATION: Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

Aegis Analytical Laboratories, Inc., 624 Grassmere Park Rd., Suite 21, Nashville, TN 37211, 615–331–5300.

Alabama Reference Laboratories, Inc., 543 South Hull St., Montgomery, AL 36103, 800–541–4931/205–263–5745.

American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 22021, 703–802–6900.

Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119–5412, 702–733–7866.

Associated Regional and University Pathologists, Inc. (ARUP), 500 Chipeta Way, Salt Lake City, UT 84108, 801–583–2787.

Baptist Medical Center—Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–227–2783 (formerly: Forensic Toxicology Laboratory Baptist Medical Center).

Bayshore Clinical Laboratory, 4555 W. Schroeder Dr., Brown Deer, WI 53223, 414–355–4444/800–877–7016.

Cedars Medical Center, Department of Pathology, 1400 Northwest 12th Ave., Miami, FL 33136, 305–325–5810.

Centinela Hospital Airport Toxicology Laboratory, 9601 S. Sepulveda Blvd., Los Angeles, CA 90045, 310–215–6020.

Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215–2802, 800–445–6917.

CompuChem Laboratories, Inc., 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–549–8263/800–833–3984 (Formerly: CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory, Roche CompuChem Laboratories, Inc., A Member of the Roche Group).

CORNING Clinical Laboratories, 4771 Regent Blvd., Irving, TX 75063, 800–526–0947 (formerly: Damon Clinical Laboratories, Damon/MetPath).

CORNING Clinical Laboratories, 875 Greentree Rd., 4 Parkway Ctr., Pittsburgh, PA 15220–3610, 800–284–

7515 (formerly: Med-Chek Laboratories, Inc., Med-Chek/Damon, MetPath Laboratories).

CORNING Clinical Laboratories, 4444 Giddings Road, Auburn Hills, MI 48326, 800–444–0106/810–373–9120 (formerly: HealthCare/Preferred Laboratories, HealthCare/MetPath).

CORNING Clinical Laboratories Inc., 1355 Mittel Blvd., Wood Dale, IL 60191, 630–595–3888 (formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories).

CORNING Clinical Laboratories, South Central Divison, 2320 Schuetz Rd., St. Louis, MO 63146, 800–288–7293 (formerly: Metropolitan Reference Laboratories, Inc.).

CORNING Clinical Laboratory, One Malcolm Ave., Teterboro, NJ 07608, 201–393–5000 (formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories).

CORNING National Center for Forensic Science, 1901 Sulphur Spring Rd., Baltimore, MD 21227, 410–536–1485 (formerly: Maryland Medical Laboratory, Inc., National Center for Forensic Science).

CORNING Clinical Laboratories, 7470–A Mission Valley Rd., San Diego, CA 92108–4406, 800–446–4728/619–686–3200 (formerly: Nichols Institute, Nichols Institute Substance Abuse Testing (NISAT), CORNING Nichols Institute).

Cox Health Systems, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800–876–3652/417–269–3093 (formerly: Cox Medical Centers).

Dept. of the Navy, Navy Drug Screening Laboratory, Great Lakes, IL, P.O. Box 88–6819, Great Lakes, IL 60088–6819, 847–688–2045/847–688–4171.

Diagnostic Services Inc., dba DSI, 4048 Evans Ave., Suite 301, Fort Myers, FL 33901, 941–936–5446/800–735–5416.

Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31604, 912–244–4468.

DrugProof, Division of Dynacare/ Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 800–898–0180/206–386–2672 (formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.).

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Rd., Warminster, PA 18974, 215–674–9310.

ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 601–236–2609.

General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6267.

Harrison Laboratories, Inc., 9930 W. Highway 80, Midland, TX 79706, 800–725–3784/915–563–3300 (formerly: Harrison & Associates Forensic Laboratories).

Jewish Hospital of Cincinnati, Inc., 3200 Burnet Ave., Cincinnati, OH 45229, 513–569–2051.

LabOne, Inc., 8915 Lenexa Dr., Overland Park, Kansas 66214, 913–888–3927 (formerly: Center for Laboratory Services, a Division of LabOne, Inc.).

Laboratory Corporation of America, 21903 68th Ave. South, Kent, WA 98032, 206–395–4000 (formerly: Regional Toxicology Services).

Laboratory Corporation of America Holdings, 1120 Stateline Rd., Southaven, MS 38671, 601–342–1286 (formerly: Roche Biomedical Laboratories, Inc.).

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 800–437–4986 (formerly: Roche Biomedical Laboratories, Inc.).

Laboratory Specialists, Inc., 113 Jarrell Dr., Belle Chasse, LA 70037, 504–392–7961.

Marshfield Laboratories, Forensic Toxicology Laboratory, 1000 North Oak Ave., Marshfield, WI 54449, 715–389–3734/800–331–3734.

MedExpress/National Laboratory Center, 4022 Willow Lake Blvd., Memphis, TN 38175, 901–795–1515.

Medical College Hospitals Toxicology Laboratory, Department of Pathology, 3000 Arlington Ave., Toledo, OH 43699–0008, 419–381–5213.

Medlab Clinical Testing, Inc., 212 Cherry Lane, New Castle, DE 19720, 302–655–5227.

MedTox Laboratories, Inc., 402 W. County Rd. D, St. Paul, MN 55112, 800–832–3244/612–636–7466.

Methodist Hospital of Indiana, Inc., Department of Pathology and Laboratory Medicine, 1701 N. Senate Blvd., Indianapolis, IN 46202, 317–929–3587.

Methodist Medical Center Toxicology Laboratory, 221 N.E. Glen Oak Ave., Peoria, IL 61636, 800–752–1835/309–671–5199.

MetroLab-Legacy Laboratory Services, 235 N. Graham St., Portland, OR 97227, 503–413–4512, 800–237–7808 (x4512).

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, Minnesota 55417, 612–725–2088.

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 805–322–4250.

Northwest Toxicology, Inc., 1141 E. 3900 South, Salt Lake City, UT 84124, 800–322–3361.

Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Ave., Eugene, OR 97440–0972, 541–687–2134.

Pathology Associates Medical Laboratories, East 11604 Indiana, Spokane, WA 99206, 509–926–2400/ 800–541–7891.

PharmChem Laboratories, Inc., 1505–A O'Brien Dr., Menlo Park, CA 94025, 415–328–6200/800–446–5177.

PharmChem Laboratories, Inc., Texas Division, 7606 Pebble Dr., Fort Worth, TX 76118, 817–595–0294 (formerly: Harris Medical Laboratory).

Physicians Reference Laboratory, 7800 West 110th St., Overland Park, KS 66210, 913–338–4070/800–821–3627.

Poisonlab, Inc., 7272 Clairemont Mesa Rd., San Diego, CA 92111, 619–279–2600/800–882–7272.

Premier Analytical Laboratories, 15201 I–10 East, Suite 125, Channelview, TX 77530, 713–457–3784 (formerly: Drug Labs of Texas).

Presbyterian Laboratory Services, 1851 East Third Street, Charlotte, NC 28204, 800–473–6640.

Puckett Laboratory, 4200 Mamie St., Hattiesburgh, MS 39402, 601–264–3856/800–844–8378.

Scientific Testing Laboratories, Inc., 463 Southlake Blvd., Richmond, VA 23236, 804–378–9130.

Scott & White Drug Testing Laboratory, 600 S. 25th St., Temple, TX 76504, 800–749–3788.

S.E.D. Medical Laboratories, 500 Walter NE, Suite 500, Albuquerque, NM 87102, 505–244–8800, 800–999–LABS.

Sierra Nevada Laboratories, Inc., 888 Willow St., Reno, NV 89502, 702–334–3400.

SmithKline Beecham Clinical Laboratories, 7600 Tyrone Ave., Van Nuys, CA 91045, 818–989–2520.

SmithKline Beecham Clinical Laboratories, 801 East Dixie Ave., Leesburg, FL 34748, 352–787–9006, (formerly: Doctors & Physicians Laboratory).

SmithKline Beecham Clinical Laboratories, 3175 Presidential Dr., Atlanta, GA 30340, 770–452–1590 (formerly: SmithKline Bio-Science Laboratories).

SmithKline Beecham Clinical Laboratories, 506 E. State Pkwy., Schaumburg, IL 60173, 847–885–2010, (formerly: International Toxicology Laboratories).

SmithKline Beecham Clinical Laboratories, 400 Egypt Rd., Norristown, PA 19403, 800–523–5447 / 610–631–4600 (formerly: SmithKline Bio-Science Laboratories).

SmithKline Beecham Clinical Laboratories, 8000 Sovereign Row, Dallas, TX 75247, 214–638–1301, (formerly: SmithKline Bio-Science Laboratories).

South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 219–234–4176,

Southwest Laboratories, 2727 W. Baseline Rd., Suite 6, Tempe, AZ 85283, 602–438–8507.

St. Anthony Hospital (Toxicology Laboratory), P.O. Box 205, 1000 N. Lee St., Oklahoma City, OK 73102, 405–272–7052.

Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 2703 Clark Lane, Suite B, Lower Level, Columbia, MO 65202, 573–882–1273.

Toxicology Testing Service, Inc., 5426 N.W. 79th Ave., Miami, FL 33166, 305–593–2260.

TOXWORX Laboratories, Inc., 6160 Variel Ave., Woodland Hills, CA 91367, 818–226–4373 (formerly: Laboratory Specialists, Inc.; Abused Drug Laboratories; MedTox Bio-Analytical, a Division of MedTox Laboratories, Inc.).

UNILAB, 18408 Oxnard St., Tarzana, CA 91356, 800–492–0800/818–343–8191 (formerly: MetWest-BPL Toxicology Laboratory).

UTMB Pathology-Toxicology Laboratory, University of Texas Medical Branch, Clinical Chemistry Division, 301 University Boulevard, Room 5.158, Old John Sealy, Galveston, Texas 77555–0551, 409–772–3197.

The following laboratory withdrew from the National Laboratory Certification Program on September 22, 1996: Laboratory Corporation of America, 13900 Park Center Rd., Herndon, VA 22071, 703–742–3100. (Formerly: National Health Laboratories Incorporated).

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 96–25719 Filed 10–4–96; 8:45 am]

BILLING CODE 4160–20–U

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID–014–06–1220–00]

Confluence Recreation Site Camping Closure and No Fires Notice

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Notice is hereby given that effective immediately, the undeveloped site in the Cascade Resource Area known as the Confluence Recreation Site is closed to camping and open fires. The closed area is generally described as follows.

At the confluence of the Payette River (Middle Fork) with the Payette River (South Fork) approximately 3 miles west of Garden Valley on the Garden Valley Road (Highway 17), Boise County, Idaho, T.9N., R.4E. Section 20, lot 1 and lot 2, Boise Meridian, Idaho.

FOR FURTHER INFORMATION CONTACT: John Fend, Area Manager, 3948 Development Avenue, Boise, Idaho 83705, telephone (208) 384–3000.

SUPPLEMENTARY INFORMATION: Past camping of this small undeveloped site has caused considerable confrontation with users and with residents of an adjacent developed residential area. Recreation users trespass across a private road and bridge to gain vehicular access to the peninsula portion of the site. This portion is very small, less than two acres, and has no sanitation facility. Open fires pose a safety hazard to the neighboring development. The site contains mixed ponderosa pine, shrubs, perennial and annual grasses. The area drys out early in the summer season and contains easily ignitable fire fuels. The intended effect of this action is to eliminate degradation by campers, and reduce the possibility of accidental wildfire and threat to the neighboring development. Day use access from river to peninsula and river and road access to northern parcel will continue. Camping closure and no fires signs will be posted at the site.

The authority for this closure is 43 CFR 8364.1. The closure is in conformance with the Cascade Resource Management Plan. It will remain in effect until rescinded or modified by the authorized officer.

Thomas M. Woodward,

Acting Cascade Resource Area Manager.

[FR Doc. 96–25564 Filed 10–4–96; 8:45 am]

BILLING CODE 4310–GG–M

[ID–010–06–2822–00–F284]

Eighth Street Fire In Ada County, ID; Emergency Closure

AGENCY: Bureau of Land Management, Interior.

ACTION: Emergency closure of roads, trails and all cross-country travel to pedestrians, equestrians, motorized vehicles, bicycles on BLM-administered lands with the perimeter of the Eighth Fire in Ada County, Idaho.

SUMMARY: All types of travel, pedestrians, equestrians, motorized vehicles, and bicycles are limited to roads and trails that are marked or posted open on pubic lands administered by the Bureau of Land Management within the boundaries of the Eighth Street Fire in Ada County, Idaho to protect the public from the exposed hazards, and to reduce erosion to soil and watershed. The area is roughly bounded by the Boise City on the southwest, Bogus Basin Road on the northwest, Rocky Canyon on the southeast and the Boise Ridge Road on the northeast.

The closure will be in effect immediately and will expire September 30, 1998, unless the authorized officer determines that the safety hazards still present a danger to users or the soil and vegetation within the burned area are insufficiently stabilized to sustain traffic. Exception to this closure, which will be posted, include vehicle use for administrative and emergency purposes. Under special circumstances, and upon request, the authorized officer may issue a permit allowing vehicle access into the area for other purposes, on a case-by-case basis. Along the perimeter of the fire, only the Rocky Canyon, Bogus Basin, and Boise Ridge Roads will remain open to vehicle traffic. All traffic on the Rocky Canyon, Bogus Basin, and Boise Ridge Roads will be confined to the roadbed and will not be permitted to travel off the road into the fire area unless the roads and trails are marked or posted open.

Definitions

(a) ''Public Lands'' mean any lands or interest in lands owned by the United States and administered by the Bureau of Land Management.

(b) ''Authorized Officer'' means an employee of the Bureau of Land Management who has been delegated the authority to perform under title 43.

(c) ''Emergency purpose'' means any military, fire, or law enforcement action requiring the use of vehicles within the burn area.

(d) ''Administrative purpose'' refers to action of an employee, agent, or

designated representative or authorized contractor of the Federal Government, in the course of their official duties.

(e) ''Market or Posted Open'' means road and trail markers or signs with arrows and trail numbers or the words ''TRAIL OPEN,'' ''AREA OPEN'' or ''ROAD OPEN'' and the international logos for open use for pedestrian, equestrian, bicyclist, motorcyclist, all terrain vehicle rider, and/or motorized vehicle.

EFFECTIVE DATE: This Emergency Closure is effective immediately through September 30, 1988.

ADDRESSES: Lower Snake River District, Boise Field Office, 3948 Development Avenue, Boise, Idaho 83705.

FOR FURTHER INFORMATION CONTACT: Jerry L. Kidd, District Manager, (208) 384–3300

SUPPLEMENTARY INFORMATION: This closure is being jointly established and administered by the Bureau of Land Management, the Boise National Forest, the Idaho Department of Lands, and Ada County. All travel on lands within the burned area of the fire administered by these agencies are similarly restricted. Authority for this closure is contained in CFR title 43, subpart 8341.2 and complies with CFR title 43, subpart 8364.1 Closure and Restriction Orders. Violation of this closure order is in accordance with CFR title 43, subpart 8360.0–7 and is punishable by a fine not to exceed $1,000 and/or imprisonment not to exceed 12 months.

Dated: September 25, 1996.

Jerry L. Kidd,

District Manager.

[FR Doc. 96–25565 Filed 10–4–96; 8:45 am]

BILLING CODE 4310–GG–M

[NM–931–07–1020–00]

New Mexico Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Council Meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972 (FACA), 5 U.S.C. Appendix 1, The Department of the Interior, Bureau of Land Management (BLM), announces a meeting of the New Mexico Resource Advisory Council (RAC). The meeting, if needed, will be on November 7 and 8, 1996 at the Amberely Suites Hotel, 7620 Pan America Freeway, Albuquerque, NM 87109. The need for this meeting will be determined at the October 10 and 11, 1996 RAC meeting. The November 7 and 8, 1996 RAC meeting, if needed, would be a continuation of the October 10 and 11, 1996 meeting. The agenda for the November 7 and 8, 1996 meeting includes continuing discussion of the results of continuing scoping comments on the New Mexico RAC Draft Standards for Rangeland Health and Guidelines for Livestock Grazing (S&G), development of revisions to the S&G as needed and a time for the public to address the RAC.

The meeting is open to the public. The time for the public to address the RAC is on the Thursday, November 7, 1996, from 3:00 p.m. to 5:00 p.m. The RAC may reduce or extend the end time of 5:00 p.m. depending on the number of people wishing to address the RAC and the length of time available. The length of time available for each person to address the RAC will be established at the start of the public comment period and will depend on how many people there are that wish to address the RAC. At the completion of the public comments the RAC may continue discussion on its Agenda items.

FOR FURTHER INFORMATION CONTACT: Bob Armstrong, New Mexico State Office, Policy and Planning Team, Bureau of Land Management, 1474 Rodeo Road, P.O. Box 27115, Santa Fe, New Mexico 87502–0115, telephone (505) 438–7436.

SUPPLEMENTARY INFORMATION: The purpose of the Resource Advisory Council is to advise the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with the management of public lands. The Council's responsibilities include providing advice on long-range planning, establishing resource management priorities and assisting the BLM to identify State and regional standards for rangeland health and guidelines for grazing management.

Dated: September 30, 1996.

Richard A. Whitley,

Acting State Director.

[FR Doc. 96–25579 Filed 10–4–96; 8:45 am]

BILLING CODE 4310–FB–M

[AZ–040–7122–00–5567; AZA 29361]

Notice of Realty Action; Proposed Sale of Public Lands; Arizona

AGENCY: Bureau of Land Management, Safford District, Arizona.

ACTION: Extension of notice.

SUMMARY: The following lands in Cochise County, Arizona have been found suitable for disposal under section 203 of the Federal Land Policy and Management Act of 1976 (90 Stat. 2750, 43 USC 1713). The land will not be offered for sale until at least 60 days after the date of this notice.

Gila and Salt River Meridian, Arizona

T. 23 S., R. 24 E.,
Sec. 10, lots 7 to 10 inclusive, W½NE¼, SW¼NE¼;
Sec. 11, lots 4 to 8 inclusive, N½, NE¼SE¼.

The area described contains 754.55 acres.

SUPPLEMENTARY INFORMATION: On Page 6257 of Vol. 61, No. 33 of the Federal Register published February 16, 1996, the Safford District Office published a notice for this public land sale. This notice segregated the subject public lands from appropriation under the public land laws, including the mining laws, pending disposition of the action or 270 days from the date of publication of the notice in the Federal Register. Upon publication of this notice in the Federal Register, that segregation will be extended pending disposition of the action or for another 270 day period, whichever occurs first.

FOR INFORMATION CONTACT: Bill Auby, Geologist, at BLM, Tucson Resource Area Office, 12661 East Broadway, Tucson, Arizona 85748; telephone number (520) 722–4289.

Dated: September 13, 1996.

Frank L. Rowley,

Acting District Manager.

[FR Doc. 96–25634 Filed 10–4–96; 8:45 am]

BILLING CODE 4310–32–M

National Park Service

Draft General Management Plan/Draft Environmental Impact Statement, Cape Cod National Seashore, Massachusetts

ACTION: Extension of public peview period and announcement of additional public meetings of the Draft Environmental Impact Statement for the Draft General Management Plan.

SUMMARY: Pursuant to Council on Environmental Quality regulations and National Park Service policy, this notice announces the extension of the public review period and announcement of additional public meetings for the draft environmental impact statement (DEIS) for the Draft General Management Plan (DGMP) for Cape Cod National Seashore, Barnstable County, Massachusetts. In accordance with the National Environmental Policy Act of 1969, the environmental impact statement was prepared to assess the impacts of implementing the general management plan.

This Draft Environmental Impact Statement for the Draft General Management Plan presents a proposal and two alternative strategies for guiding future management of Cape Cod National Seashore and balancing resource protection and public use. The major subject areas are natural and cultural resources, public use, nonfederal lands, and park management and operations.

DATES AND MEETINGS: The DGMP and DEIS was made available for public review on August 19, 1996. The 75-day review period has been extended by 30 days; comments should be received no later than November 30, 1996. Two additional public meetings are to be held on October 24, 1996 and November 21, 1996 at the following locations:

Truro Central School, Route 6, Truro, MA, Thursday, October 24, 1996, 7–9 p.m.

Nauset Regional High School, 100 Cable Road, No. Eastham, MA, Thursday, November 21, 1996, 7–9 p.m.

SUPPLEMENTARY INFORMATION: Comments on the DGMP and the DEIS shall be submitted to: Ms. Maria Burks, Superintendent, Cape Cod National Seashore, South Wellfleet, MA 02663, (508) 349–3785.

Dated: October 1, 1996.

Linda Canzanelli,

Acting Superintendent, Cape Cod National Seashore.

[FR Doc. 96–25597 Filed 10–04–96; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Ixtlera de Santa Catarina, S.A. de C.V. and MFC Corporation; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S. § 16(b)-(h), that a proposed Final Consent Judgment, Stipulation and Competitive Impact Statement have been filed with the United States District Court for the Eastern District of Pennsylvania in the above-captioned case.

On September 26, 1996, the United States filed a civil antitrust Complaint to prevent and restrain Ixtlera de Santa Catarina, S.A. de C.V. (''Ixtlera'') and MFC Corporation from conspiring to fix prices and allocate the sales volume of tampico fiber imported and sold in the United States in violation of Section 1 of the Sherman Act (15 U.S.C. § 1). Tampico fiber is a vegetable fiber grown in Mexico and used as a filler in industrial and consumer brushes.

The Complaint alleges that the defendants agreed with unnamed co-conspirators to (1) fix the prices of tampico fiber imported into the United States; (2) fix the resale prices charged in the United States distributors; and (3) allocate tampico fiber sales among United States distributors.

The proposed Final Judgment would prohibit the defendants from entering into any agreement or understanding with any other processor or distributor of tampico fiber to:

(1) Raise, fix, or maintain the price or other terms or conditions for the sale or supply of tampico fiber;

(2) Allocate sales, territories or customers for tampico fiber;

(3) Eliminate or discourage new entry into the tampico fiber market; and

(4) Eliminate or otherwise restrict the supply of tampico fiber to any customer.

The proposed Final Judgment would also prohibit defendants form communicating with any other processor, supplier or distributor regarding future price information, information regarding sales volume, the location or identity of customers, eliminating or discouraging new entrants into the tampico fiber market, or eliminating or restricting the supply of tampico fiber to any customer. In addition, the proposed Final Judgment would prohibit the defendants from adhering to any resale pricing policy and defendant Ixtlera from suggesting resale prices and form terminating or threatening to terminate any distributor for that distributor's pricing. Finally, the proposed Final Judgment would also prohibit Ixtlera from merging with the Mexican tampico fiber processor Fibras Saltillo, S.A. de C.V. without providing the Antitrust Division with ninety (90) days notice to review the transaction.

Public comment is invited within the statutory sixty (60) day period. Such comments will be published in the Federal Register and filed with the Court. Comments should be addressed to Robert E. Connolly, Chief, Middle Atlantic Office, U.S. Department of Justice, Antitrust Division, The Curtis Center, 6th and Walnut Streets, Suite 650 West, Philadelphia, PA 19106 (telephone number 215–597–7405).

Rebecca P. Dick,

Deputy Director of Operations.

In the United States District Court for the Eastern District of Pennsylvania

United States of America, Plaintiff, v. Ixtlera de Santa Catarina, S.A. de C.V.; and MFC Corporation, Defendants. Civil Action No. 95–6515, Judge Jay C. Waldman.

Stipulation

It is stipulated by and between the undersigned parties, by their respective attorneys, that:

(1) The parties consent that a final judgment in the form hereto attached may be filed and entered by the Court at any time after the expiration of the sixty (60) day period for public comment provided by the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b)–(h), without further notice to any party or other proceedings, either upon the motion of any party or upon the Court's own motion, provided that plaintiff has not withdrawn its consent as provided herein;

(2) The plaintiff may withdraw its consent hereto at any time within said period of sixty (60) days by serving notice thereof upon the other party hereto and filing said notice with the Court;

(3) In the event the plaintiff withdraws its consent hereto, this application shall be of no effect whatever in this or any other proceeding and the making of this stipulation shall not in any manner prejudice any consenting party to any subsequent proceedings.

Dated: September 26, 1996.

For the Plaintiff:

Joel I. Klein,

Acting Assistant Attorney General.

Rebecca P. Dick,

Deputy Director of Operations.

Robert E. Connolly,

Chief, Middle Atlantic Office.

Respectfully submitted,

Edward S. Panek,

Michelle A. Pionkowski,

Roger L. Currier,

Joseph Muoio,

Attorneys, Antitrust Division, U.S. Department of Justice, Middle Atlantic Office, The Curtis Center, Suite 650W, 7th and Walnut Streets, Philadelphia, PA 19106, Tel.: (215) 597–7401.

For the Defendants:

Gordon B. Spivack,

Ixtlera de Santa Catarina, S.A. de C.V.

Roxann E. Henry,

MFC Corporation.

Final Judgment

Plaintiff, the United States of America, filed its complaint on September 26, 1996. Plaintiff and defendants, by their respective attorneys, have consented to the entry of this final judgment without trial or adjudication of any issue of fact or law. This final judgment shall not be evidence against or an admission by any party to any issue of fact or law.

Defendants have agreed to be bound by the provisions of this final judgment pending its approval by the Court.

Therefore, before the taking of any testimony and without trial or adjudication of any such issue of fact or law herein, and upon consent of the parties, it is hereby *ordered, adjudged, and decreed* as follows:

I

Jurisidiction

This Court has jurisdiction of the subject matter of this action and of each of the parties consenting hereto. The complaint states a claim upon which relief may be granted against defendants under Section 1 of the Sherman Act, 15 U.S.C. § 1.

II

Definitions

As used in this final judgment:

A. ''Agreement'' means any contract, agreement or understanding, whether oral or written, or any term or provision thereof.

B. ''Person'' means any individual, corporation, partnership, company, sole proprietorship, firm or other legal entity.

C. ''Tampico fiber'' is a natural vegetable fiber produced by the lechugilla plant and grown in the deserts of northern Mexico. It is harvested by individual farmers, processed, finished and exported to the United States and worldwide, where it is used as brush filling material for industrial and consumer brushes. It is available in natural white, bleached white, black, gray and a wide variety of mixtures.

D. ''Resale price'' means any price, price floor, price ceiling, price range, or any mark-up, formula or margin of profit relating to tampico fiber sold by distributors.

III

Applicability

A. This final judgment applies to each of the defendants and to their owners, officers, directors, agents, employees, subsidiaries, successor and assigns, and to all other persons in active concert or participation with any of them who shall have received actual notice of this final judgment by personal service or otherwise.

B. Each defendant shall require, as a condition of any sale or other disposition of all, or substantially all, of its stock or assets used in the manufacture or sale of tampico fiber, that the acquiring party or parties agree to be bound by the provisions of this final judgment, and that such agreement be filed with the Court.

IV

Prohibited Conduct

As to tampico fiber imported into or sold in the United States:

A. Each defendant is enjoined and restrained from directly or indirectly entering into, adhering to, maintaining, furthering, enforcing or claiming any rights under any contract, agreement, arrangement, understanding, plan, program, combination or conspiracy with any other processor, supplier or distributor of tampico fiber to:

(1) Raise, fix, or maintain the prices or other terms or conditions for the sale or supply of tampico fiber;

(2) Allocate sales volumes, territories or customers for tampico fiber;

(3) Discourage or eliminate any new entrant into the tampico fiber market; or

(4) Restrict or eliminate the supply of tampico fiber to any customer;

B. Each defendant is enjoined and restrained from communication with any processor, supplier or distributor (other than its own processor, supplier or distributor) of tampico fiber regarding any current or future price, price change, discount, or other term or condition of sale charged or quoted or to be charged or quoted to any customer or potential customer for tampico fiber, whether communicated in the form of a specific price or in the form of information from which such specific price may be computed;

C. Each defendant is enjoined and restrained from distributing to any processor, supplier or distributor (other than its own processor, supplier or distributor) of tampico fiber price lists or other pricing material that is used, has been used, or will be used in computing prices or terms or conditions of sale charged or to be charged for tampico fiber;

D. Each defendant is enjoined and restrained from communicating with any processor, supplier or distributor (other than its own processor, supplier or distributor) of tampico fiber regarding information pertaining to the volume of sales of tampico fiber or the location or identity of customers;

E. Each defendant is enjoined and restrained from communicating with any processor, supplier or distributor regarding discouraging or eliminating any new entrant into the tampico fiber market or restricting or eliminating the supply of tampico fiber to any customer;

F. Ixtlera is enjoined and restrained from directly or indirectly entering into, adhering to, maintaining, furthering, enforcing or claiming any right under any contract, agreement, understanding, plan or program with any distributor to fix or maintain the prices at which tampico fiber sold by Ixtlera may be resold or offered for sale by any distributor;

G. Ixtlera is enjoined and restrained from directly or indirectly adopting, promulgating, suggesting, announcing or establishing any resale pricing policy for tampico fiber;

H. Ixtlera is enjoined and restrained from threatening any distributor with termination or terminating any distributor on the basis of that distributor's pricing; or discussing with any present or potential distributor any decision regarding termination of any other distributor for any reason directly or indirectly related to the other distributor's resale pricing, provided, however, that nothing herein shall prohibit Ixtlera from terminating a distributor for any reason other than the distributor's resale pricing;

I. MFC is enjoined and restrained from directly or indirectly entering into, adhering to, maintaining, furthering, enforcing or claiming any right under any contract, agreement, understanding, plan or program with any supplier to fix or maintain the prices at which tampico fiber may be resold or offered for sale by MFC or any other distributor;

J. Each defendant is enjoined and restrained from participating or engaging directly or indirectly through any trade association, organization or other group in any activity which is prohibited in IV (A)–(I) above; and

K. Ixtlera is enjoined and retrained from merging with, acquiring all or part of the assets or securities of, or selling all or part of its assets or securities to the Mexican tampico fiber processor Fibras Saltillo, S.A. de C.V., or its owners, officers, directors, agents, employees, subsidiaries, successors and assigns without first providing plaintiff with at least 90 days written notice prior to closing the transaction for the purpose of investigation the proposed transaction. Such notification shall include a complete description, English, of the proposed transaction and the reasons therefor. Ixtlera agrees to provide promptly all information, with English translations, reasonably requested by plaintiff in connection with its investigation of the proposed transaction, consents to the jurisdiction of the Court to adjudicate the legality of the proposed or consummated transaction under the antitrust laws of the United States and waives any objections to venue. Nothing in this paragraph shall prohibit Miguel Schwarz, Marx, principal of Ixtlera, from divesting to any person, without

notice, the 27.5 percent interest in Fibras Saltillo, S.A. de C.V. which he currently holds.

V

Permitted Conduct

A. Other than Section IV(A) of this final judgment, nothing contained in this final judgment shall prohibit a defendant from negotiating or communicating with any processor, supplier or distributor of tampico fiber or with any agent, broker or representative of such processor, supplier or distributor solely in connection with *bona fide* proposed or actual purchases of tampico fiber from, or sale or tampico fiber to, that processor, supplier or distributor.

B. Nothing contained in this final judgment shall prohibit defendant MFC from unilaterally deciding to resell tampico fiber at prices suggested by its supplier. However, any instance in which a supplier suggests the prices at which MFC should resell tampico fiber shall be reported in writing with a copy to MFC's Antitrust Compliance Officer. This report shall state the date, time and place of the communication, whether it was oral or written, the name and title of the other person or persons involved in the communication, briefly describe the pricing information provided, and if the communication was written, have attached a copy of the document containing the reference to the suggested resale prices. Such reports shall be retained in the files of MFC, and copies thereof shall be delivered to the Antitrust Division by the defendant on or about each anniversary date of this final judgment.

C. Nothing contained in this final judgment shall prohibit Miguel Schwarz Marx from obtaining information as to the prices Fibras Saltillo charged A&L Mayer Associates, Inc. or any successor to A&L Mayer Associates, Inc. that serves as a conduit between Fibras Saltillo and its United States distributor for tampico fiber so long as the pricing information is at least six months old and is used solely to protect the value of Schwarz's investment in Fibras Saltillo under Mexican law.

D. Nothing contained in this final judgment shall prevent (1) MFC from being Ixtlera's exclusive distributor for tampico fiber in the United States, (2) MFC and Ixtlera from conducing negotiations regarding such an exclusive distributorship, or (3) Ixtlera from deciding to appoint another company as its exclusive distributor in the United States.

VI

Compliance Program

Each defendant shall establish within thirty (30) days of entry of this final judgment and shall thereafter for so long as it or its employees are engaged in the manufacture or sale of tampico fiber, maintain a program to insure compliance with this final judgment, which program shall include at a minimum the following:

A. Designating an Antitrust Compliance Officer responsible, on a continuing basis, for achieving compliance with this final judgment and promptly reporting to the Department of Justice any violation of the final judgment;

B. Within sixty (60) days after the date of entry of this final judgment, furnishing a copy thereof to each of its own, its subsidiaries', and its affiliates' (1) officers, (2) directors, and (3) employees or managing agents who are engaged in, or have responsibility for or authority over, the pricing of tampico fiber; and advising and informing each such person that his or her violation of this final judgment could result in a conviction for contempt of court and imprisonment, a fine, or both;

C. Within seventy five (75) days after the date of entry of this final judgment, certifying to the plaintiff whether it has designated an Antitrust Compliance officer and has distributed the final judgment in accordance with Sections VI (A) and (B) above;

D. Within thirty (30) days after each such person becomes an officer, director, employee or agent of the kind described in Section VI (B), furnishing to him or her a copy of this final judgment together with the advice specified in Section VI (B);

E. Annually distributing the final judgment to each person described in Sections VI (B) and (D);

F. Annually briefing each person described in Sections VI (B) and (D) as to the defendant's policy regarding compliance with the Sherman Act and with this final judgment, including the advice that such defendant will make legal advice available to such persons regarding any compliance questions or problems;

G. Annually obtaining (and maintaining) from each person described in Sections VI (B) and (D) a certification that he or she:

(1) Has read, understands, and agrees to abide by the terms of this final judgment;

(2) Has been advised of and understands the company's policy with respect to compliance with the Sherman Act and the final judgment;

(3) Has been advised and understands that his or her non-compliance with the final judgment may result in conviction for criminal contempt of court and imprisonment, a fine, or both; and

(4) Is not aware of any violation of the final judgment that has not been reported to the Antitrust Compliance Officer; and

H. On or about each anniversary date of the entry of the final judgment, submitting to the plaintiff an annual declaration as to the fact and manner of its compliance with this final judgment, including any reports responsive to Section V of this final judgment.

VII

Inspection and Compliance

For the purpose of determining or securing compliance with this final judgment and subject to any legally recognized privilege, from time to time:

A. Duly authorized representatives of the Department of Justice shall, upon written request of the Attorney General or of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to a defendant made to its principal office, be permitted:

(1) Access, during office hours of such defendant, to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of such defendant, which may have counsel present, relating to any matters contained in this final judgment; and

(2) Subject to the reasonable convenience of such defendant and without restraint or interference from it, to interview officers, employees and agents of such defendant, who may have counsel present, regarding any such matters;

B. Upon the written request of the Attorney General or of the Assistant Attorney General in charge of the Antitrust Division made to a defendant's principal office, such defendant shall submit such written reports, under oath if requested, with respect to any of the matters contained in this final judgment, as may be requested;

C. No information or documents obtained by the means provided in this Section VII of the final judgment shall be divulged by any representative of the Department of Justice to any person other than a duly authorized representative of the Executive Branch of the United States, except in the course of legal proceedings to which the United States is a party, or for the purpose of securing compliance with this final judgment, or as otherwise required by law;

D. If at the time information or documents are furnished by a defendant to plaintiff, such defendant represents and identifies in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(7) of the Federal Rules of Civil Procedure, and such defendant marks each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(7) of the Federal Rules of Civil Procedure,'' then ten (10) days notice shall be given by plaintiff to such defendant prior to divulging such material in any legal proceeding (other than a grand jury proceeding) to which such defendant is not a party; and

E. Nothing set forth in this final judgment shall prevent the Antitrust Division from utilizing other investigative alternatives, such as Civil Investigative Demand process provided by 15 U.S.C. §§ 1311–1314 or a federal grand jury, to determine if the defendant has complied with this final judgment.

VIII

Retention of Jurisdiction

Jurisdiction is retained by this Court for the purpose of: (1) enabling any of the parties to this final judgment to apply to this Court at any time for such further orders or directions as may be necessary or appropriate for the construction or carrying out of this final judgment, for the modification of any of the provisions hereof, for the enforcement of compliance herewith, and for the punishment of violations hereof; and (2) adjudicating the legality of any merger or acquisition of assets or securities described in Section IV (K) above.

IX

Ten Year Expiration

This final judgment will expire on the tenth anniversary of its date of entry.

X

Public Interest

Entry of this final judgment is in the public interest.

Dated: _____

_____

United States District Judge

Competitive Impact Statement

Pursuant to Section 2 of the Antitrust Procedures and Penalties Act (''APPA''), 15 U.S.C. § 16(b), the United States files this Competitive Impact Statement relating to the proposed final judgment as to *United States* v. *Ixtlera de Santa Catarina, S.A. de C.V. and MFC Corporation,* submitted for entry in this civil antitrust proceeding.

I

Nature and Purpose of the Proceedings

On September 26, 1996, the United States filed a civil antitrust complaint alleging that under Section 4 of the Sherman Act, as amended, 15 U.S.C. § 4, the above-named defendants combined and conspired with others from at least as early as January 1990 to April 1995, to lessen and eliminate competition in the sale of tampico fiber in the United States, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. A companion criminal information against Ixtlera de Santa Catarina, S.A. de C.V. (''Ixtlera'') and MFC Corporation (''MFC'') was filed on September 26, 1996. The civil complaint alleges that as part of the conspiracy, the defendants and co-conspirators among other things:

(a) Fixed the prices at which tampico fiber was imported into the United States;

(b) Fixed the resale prices for tampico fiber charged by their exclusive United States distributors; and

(c) Allocated sales between such distributors.

The complaint seeks a judgment by the Court declaring that the defendants engaged in unlawful combinations and conspiracies in restraint of trade in violation of the Sherman Act. It also seeks an order by the Court to enjoin and restrain the defendants from any such activities or other activities having a similar purpose or effect in the future.

The United States and defendants have stipulated that the proposed final judgment may be entered after compliance with the APPA, unless the United States withdraws its consent.

The Court's entry of the proposed final judgment will terminate this civil action against these defendants, except that the Court will retain jurisdiction over the matter for possible further proceedings to construe, modify or enforce the judgment, or to punish violations of any of its provisions.

II

Description of the Practices Giving Rise to the Alleged Violations of the Antitrust Laws

As defined in the complaint, tampico fiber is a natural vegetable fiber produced by the lechuguilla plant and grown in the deserts of northern Mexico. It is harvested by individual farmers, processed, finished and exported worldwide, where it is used as brush filling material for industrial and consumer brushes. It is available in natural white, bleached white, black, gray and a wide variety of mixtures.

The complaint further alleges that defendant MFC had United States sales of tampico fiber of approximately $14,699,000 during the period from January of 1990 through April of 1995. During this time, the defendants sold and shipped substantial quantities of tampico fiber in a continuous and uninterrupted flow of interstate commerce from the processing facility of Ixtlera in Mexico through its exclusive United States distributor, MFC, a company headquartered in Texas, to MFC's customers throughout the United States, including those located in the Eastern District of Pennsylvania. Similarly, the complaint alleges that non-defendant co-conspirators sold and shipped additional substantial quantities of tampico fiber in a continuous and uninterrupted flow of interstate commerce from another processing facility in Mexico through their exclusive United States distributor to customers throughout the United States, including some located in the Eastern District of Pennsylvania.

The complaint alleges that the defendants and co-conspirators engaged in three forms of concerted action and states three causes of action: (1) An agreement to fix import prices, (2) an agreement to fix resale prices, and (3) an agreement to allocate sales. Essentially, the complaint alleges that defendants and their co-conspirators fixed the prices at which tampico fiber was sold to their two respective exclusive United States distributors, agreed on the resale prices to be charged by those two distributors and agreed to a percentage allocation of sales volume between those distributors.

The defendants and their co-conspirators went far beyond suggesting and adhering to suggested resale prices. Resale price sheets were provided by Ixtlera and the co-conspirator processor to MFC and the co-conspirator distributor. As a condition of becoming and remaining a United States distributor of tampico fiber, the co-conspirator distributor agreed by written contract with its supplier to sell at the prices listed on the price sheet. From at least January 1990 on, both MFC and the co-conspirator distributor had identical price sheets supplied by Ixtlera and the co-conspirator processor, and the majority of tampico fiber sales were made by those distributor at these list prices or other agreed-upon prices. MFC made the sales with its two top executives' knowledge of and participation in the collusive agreement with their putative competitor.

The use of resale price maintenance by the defendants and co-conspirators was designed to and had the effect of monitoring and enforcing the horizontal

price-fixing and sales volume allocation agreements between the defendants and co-conspirators. The defendants' conduct had the effect of lessening or eliminating competition between the two United States distributors of tampico fiber in order to maintain prices at artificially high and non-competitive levels.

In furtherance of the conspiracy, the defendants and their co-conspirators, among other things, periodically met, discussed and agreed to new import and resale prices for tampico fiber, and met, discussed and compared the annual sales volumes of their United States distributors to ensure they were at or about the percentages the defendants and co-conspirators had agreed upon for each.

III

Explanation of the Proposed Final Judgment

The United States and the defendants have stipulated that a final judgment, in the form filed with the Court, may be entered by the Court at any time after compliance with the APPA, 15 U.S.C. § 16(b)–(h). The proposed final judgment provides that the entry of the final judgment does not constitute any evidence against or an admission by any party with respect to any issue of fact or law. Under the provisions of Section 2(e) of the APPA, entry of the proposed final judgment is conditioned upon the Court finding that its entry will be in the public interest.

The United States has filed a criminal information charging Ixtlera, MFC and unnamed co-conspirators with a conspiracy to fix the prices and allocate sales of tampico fiber imported into and sold in the United States, in violation of the Sherman Act (15 U.S.C. § 1).

The United States does not routinely file both civil and criminal cases involving the same underlying conduct. It is appropriate to do so in this case, however, because of the extent of the control of the market by a small number of companies conspiring to eliminate price competition in the sale of tampico fiber in the United States through a comprehensive scheme of fixing the prices of imported tampico fiber, allocating sales volumes between their exclusive distributors, and agreeing upon the prices at which distributors would resell tampico fiber within the United States.

The proposed final judgment contains three principal forms of relief. First, the defendants are enjoined from repeating the conduct they undertook in connection with the tampico fiber conspiracy and from certain other conduct that could have similar anticompetitive effects. Second, in light of their overwhelming shares of the tampico fiber market in the United States and of evidence that they have previously discussed consolidating operations, Ixtlera is prohibited from merging with its co-conspirator processor, Fibras Saltillo, S.A. de C.V., without providing the Antitrust Division ninety (90) days notice. Such a transaction, if consummated, would likely nullify the prophylactic measures pertaining to horizontal conduct contained in both this proposed final judgment and the final judgment entered by the Court against Fibras Saltillo on August 20, 1996. Third, the proposed final judgment places affirmative burdens on the defendants to pursue an antitrust compliance program directed toward avoiding a repetition of the tampico fiber conspiracy.

A. Prohibited Conduct

Section IV of the proposed final judgment broadly enjoins each defendant from conspiring to fix prices, allocate sales, discourage or eliminate new entrants, or otherwise restrict or eliminate the supply of tampico fiber sold to any customer in the United States, (IV (A)); from communicating pricing, sales volume and customer information to any processor, supplier or distributor of tampico fiber other than its own (IV (B), (C) and (D)); from communicating regarding discouraging or eliminating new entrants (IV (E)); from engaging in resale price maintenance (IV (F)–(I)); and from joining any group whose aims or activities are prohibited by Sections IV (A)–(I) of the proposed final judgment (IV (J)). Finally, Ixtlera is enjoined from merging with, acquiring the stock or assets of, or selling its stock or assets to Fibras Saltillo, S.A. de C.V., a major processor of tampico fiber and a co-conspirator, without providing the Antitrust Division ninety (90) days notice.

Specifically, as regards tampico fiber sold in the United States, Sections IV (A)–(E) of the proposed final judgment provide as follows:

Section IV (A) of the proposed final judgment enjoins each defendant from agreeing with any other processor, supplier or distributor of tampico fiber to (1) raise, fix, or maintain the prices or other terms or conditions for the sale or supply of tampico fiber; (2) allocate sales volumes, territories or customers for tampico fiber; (3) discourage or eliminate any new entrant into the tampico fiber market; or (4) restrict or eliminate the supply of tampico fiber to any customer.

Section IV (B) of the proposed final judgment enjoins each defendant from communicating with any processor, supplier or distributor (other than its own processor, supplier or distributor) of tampico fiber regarding any current or future price, price change, discount, or other term or condition of sale charged or quoted or to be charged or quoted to any customer or potential customer for tampico fiber, whether communicated in the form of a specific price or in the form of information from which such specific price may be computed.

Section IV (C) of the proposed final judgment enjoins each defendant from distributing to any processor, supplier or distributor (other than its own processor, supplier or distributor) of tampico fiber price lists or other pricing material that is used, has been used, or will be used in computing prices or terms or conditions of sale charged or to be charged for tampico fiber.

Section IV (D) of the proposed final judgment enjoins each defendant from communicating with any processor, supplier or distributor (other than its own processor, supplier or distributor) of tampico fiber regarding information pertaining to the volume of sales of tampico fiber or the location or identity of customers.

Section IV (E) of the proposed final judgment enjoins each defendant from communicating with any processor, supplier or distributor regarding discouraging or eliminating any new entrant into the tampico fiber market or restricting or eliminating the supply of tampico fiber to any customer.

Section IV (F) of the proposed final judgment enjoins Ixtlera from directly or indirectly entering into, adhering to, maintaining, furthering, enforcing or claiming any right under any contract, agreement, understanding, plan or program with any distributor to fix or maintain the prices at which tampico fiber sold by Ixtlera may be resold or offered for sale by any distributor.

Section IV (G) of the proposed final judgment enjoins Ixtlera from directly or indirectly adopting, promulgating, suggesting, announcing or establishing any resale pricing policy for tampico fiber.

Section IV (H) of the proposed final judgment enjoins Ixtlera from threatening any distributor with termination or terminating any distributor on the basis of that distributor's pricing; or discussing with any present or potential distributor any decision regarding termination of any other distributor for any reason directly or indirectly related to the latter distributor's resale pricing, provided, however, that nothing herein shall

prohibit Ixtlera from terminating a distributor for any reason other than the distributor's resale pricing;

Section IV (I) of the proposed final judgment enjoins MFC from directly or indirectly entering into, adhering to, maintaining, furthering, enforcing or claiming any right under any contract, agreement, understanding, plan or program with any supplier to fix or maintain the prices at which tampico fiber may be resold or offered for sale by MFC or any other distributor.

Section IV (J) of the proposed final judgment enjoins each defendant from participating or engaging directly or indirectly through any trade association, organization or other group in any activity which is prohibited in IV (A)–(I).

Section IV (K) of the proposed final judgment enjoins Ixtlera from merging with, acquiring all or part of the assets or securities of, or selling all or part of its assets or securities to the Mexican tampico fiber processor Fibras Saltillo, S.A. de C.V., or its owners, officers, directors, agents, employees, subsidiaries, successors and assigns without first providing plaintiff with at least ninety (90) days written notice prior to closing the transaction. Such notification shall include a complete description, in English, of the proposed transaction and the reasons therefor. Ixtlera agrees to provide promptly all information, with English translations, reasonably requested by plaintiff in connection with its investigation of the proposed transaction, consents to the jurisdiction of the Court to adjudicate the legality of the proposed or consummated transaction under the antitrust laws of the United States, and waives any objections to venue. Nothing in this paragraph shall prohibit Miguel Schwarz Marx, principal of Ixtlera, from divesting to any person, without notice, the 27.5 percent interest in Fibras Saltillo, S.A. de C.V. which he currently holds.

B. Permitted Conduct

Four exceptions to the broad prohibitions of Section IV of the proposed final judgment are contained in Section V.

Section V (A) permits any necessary negotiations or communications with any processor, supplier or distributor of tampico fiber or with any agent, broker or representative of such processor, supplier or distributor in connection with *bona fide* proposed or actual purchases of tampico fiber from, or sale of tampico fiber to, that processor, supplier or distributor.

Section V (B) makes it clear that nothing contained in the proposed final judgment would prohibit MFC from unilaterally deciding to resell tampico fiber at prices suggested by its supplier. However, any instance of this must be reported and the reports must be retained in MFC's files.

Section V (C) makes it clear that although Miguel Schwarz Marx, an owner and officer of Ixtlera, is otherwise prohibited from discussing with or obtaining information from Fibras Saltillo regarding Fibras Saltillo's prices, volume, customers or marketing plans for tampico fiber (IV (A)–(E)), as a 27.5 percent owner of Fibras Saltillo, he can have limited access to historical pricing information of Fibras Saltillo to A&L Mayer Associates, Inc. (Associates) or Associates successor that serves as a conduit between Fibras Saltillo and its United States distributor (currently Brush Fibers, Inc.), provided such information is at least six months old and is used solely to protect the value of Schwarz's investment in Fibras Saltillo under Mexican law.

Section V (D) makes it clear that nothing contained in the final judgment would prevent (1) MFC from continuing to act as Ixtlera's exclusive distributor for tampico fiber in the United States; (2) MFC and Ixtlera from conducting negotiations regarding such an exclusive distributorship; or (3) Ixtlera from deciding to appoint another company as its exclusive distributor in the United States.

C. Defendants' Affirmative Obligations

Section VI requires that within thirty (30) days of entry of the final judgment, the defendants adopt or pursue an affirmative compliance program directed toward ensuring that their employees comply with the antitrust laws. More specifically, the program must include the designation of an Antitrust Compliance Officer responsible for compliance with the final judgment and reporting any violations of its terms. It further requires that each defendant furnish a copy of the final judgment to each of its officers and directors and each of its employees who is engaged in or has responsibility for or authority over pricing of tampico fiber within sixty (60) days of the date of entry, and to certify that it has distributed those copies and designated an Antitrust Compliance Officer within seventy-five (75) days. Copies of the final judgment also must be distributed to anyone who becomes such an officer, director or employee within thirty (30) days of holding that position and to all such individuals annually.

Furthermore, Section VI requires each defendant to brief each officer, director and employee engaged in or having responsibility over pricing of tampico fiber as to the defendant's policy regarding compliance with the Sherman Act and with the final judgment, including the advice that his or her violation of the final judgment could result in a conviction for contempt of court and imprisonment, a fine or both and that the defendant will make legal advice available to such persons regarding compliance questions or problems. The defendants annually must obtain (and maintain) certifications from each such person that the aforementioned briefing, advice and a copy of the final judgment were received and understood and that he or she is not aware of any violation of the final judgment that has not been reported to the Antitrust Compliance Officer. Finally, each defendant must submit to the plaintiff an annual declaration as to the fact and manner of its compliance with the final judgment.

Under Section VII of the final judgment, the Justice Department will have access, upon reasonable notice, to the defendants' records and personnel in order to determine defendants' compliance with the judgment.

D. Scope of the Proposed Judgment

(1) Persons Bound by the Decree

The proposed judgment expressly provides in Section III that its provisions apply to each of the defendants and each of their owners, officers, directors, agents and employees, subsidiaries, successors and assigns and to all other persons who receive actual notice of the terms of judgment.

In addition, Section III of the judgment prohibits each of the defendants from selling or transferring all or substantially all of its stock or assets used in its tampico fiber business unless the acquiring party files with the Court its consent to be bound by the provisions of the judgment.

(2) Duration of the Judgment

Section IX provides that the judgment will expire on the tenth anniversary of its entry.

E. Effect of the Proposed Judgment on Competition

The prohibition terms of Section IV of the final judgment are designed to ensure that each defendant will act independently in determining the prices, and terms and conditions at which it will sell or offer to sell tampico fiber, and that there will be no anticompetitive restraints (horizontal or vertical) in the tampico fiber market. The affirmative obligations of Sections

VI and VII are designed to ensure that each corporate defendant's employees are aware of their obligations under the decree in order to avoid a repetition of the conspiracies in the tampico fiber industry that led to this case and the companion criminal proceeding. Compliance with the proposed judgment will deter price collusion, allocation of sales, markets and customers, concerted activities in restricting new entrants and customers, and resale price restraints by each of the defendants with each other and with other tampico fiber processors and/or distributors.

IV

Remedies Available to Potential Private Plaintiffs

After entry of the proposed final judgment, any potential private plaintiff who might have been damaged by the alleged violation will retain the same right to sue for monetary damages and any other legal and equitable remedies which he or she may have had if the proposed judgment had not been entered. The proposed judgment may not be used, however, as *prima facie* evidence in private litigation, pursuant to Section 5(a) of the Clayton Act, as amended, 15 U.S.C. § 16(a).

V

Procedures Available for Modification of the Proposed Consent Judgment

The proposed final judgment is subject to a stipulation between the government and the defendants which provides that the government may withdraw its consent to the proposed judgment any time before the Court has found that entry of the proposed judgment is in the public interest. By its terms, the proposed judgment provides for the Court's retention of jurisdiction of this action in order to permit any of the parties to apply to the Court for such orders as may be necessary or appropriate for the modification of the final judgment.

As provided by the APPA (15 U.S.C. § 16), any person wishing to comment upon the proposed judgment may, for a sixty-day (60) period subsequent to the publishing of this document in the Federal Register, submit written comments to the United States Department of Justice, Antitrust Division, Attention: Robert E. Connolly, Chief, Middle Atlantic Office, Suite 650 West, 7th and Walnut Streets, Philadelphia, Pennsylvania 19106. Such comments and the government's response to them will be filed with the Court and published in the Federal Register. The government will evaluate all such comments to determine whether there is any reason for it to withdraw its consent to the proposed judgment.

VI

Alternative to the Proposed Final Judgment

The alternative to the proposed final judgment considered by the Antitrust Division was a full trial of the issues on the merits and on relief. The Division considers the substantive language of the proposed judgment to be of sufficient scope and effectiveness to make litigation on the issues unnecessary, as the judgment provides appropriate and fully effective relief against the violations alleged in the complaint.

VII

Determinative Materials and Documents

No materials or documents were considered determinative by the United States in formulating the proposed Final Judgment. Therefore, none are being filed pursuant to the APPA, 15 U.S.C. § 16(b).

Dated: _____

Joel I. Klein,

Acting Assistant Attorney General.

Rebecca P. Dick,

Deputy Director of Operations.

Robert E. Connolly,

Chief, Middle Atlantic Office.

Respectfully submitted,

Edward S. Panek,

Michelle A. Pionkowski,

Roger L. Currier,

Joseph Muoio,

Attorneys, Antitrust Division, U.S. Department of Justice, Middle Atlantic Office, The Curtis Center, Suite 650W, 7th and Walnut Streets, Philadelphia, PA 19106, Tel.: (215) 597–7401.

Certificate of Service

I, Edward S. Panek, an attorney with the United States Department of Justice, Antitrust Division, hereby certify that on September 26, 1996, copies of the Complaint, Stipulation, Proposed Final Judgment and Competitive Impact Statement were served, by mail, on counsel of record as follows.

Counsel for Ixtlera de Santa Catarina, S.A. de C.V.:

Gordon B. Spivack, Esquire, Coudert Brothers, 1114 Avenue of the Americas, New York, NY 10036–7703

Counsel for MFC Corporation:

Roxann E. Henry, Esquire, Howrey & Simon, 1299 Pennsylvania Avenue, NW., Washington, DC 20004–2402

Edward S. Panek,

Attorney, Antitrust Division, U.S. Department of Justice, Middle Atlantic Office, The Curtis Center, Suite 650W, 7th and Walnut Streets, Philadelphia, PA 19106, Tel.: (215) 597–7401.

[FR Doc. 96–25336 Filed 10–4–96; 8:45 am]

BILLING CODE 4410–01–M

LIBRARY OF CONGRESS

Copyright Office

[Docket No. 96–5]

Publication of Catalog of Copyright Entries

AGENCY: Copyright Office, Library of Congress.

ACTION: Notice of policy decision.

SUMMARY: Under section 707(a) of the Copyright Act, the Copyright Office is directed to publish a catalog of copyright entries at periodic intervals. The Copyright Office has determined that this statutory obligation is satisfied by electronic publication of copyright information over the Internet. For this reason, the Copyright Office is discontinuing its publication of microfiche copies of the Catalog of Copyright Entries.

EFFECTIVE DATE: October 7, 1996.

FOR FURTHER INFORMATION CONTACT: Kent Dunlap, Principal Legal Advisor to the General Counsel's Office, Copyright GC/I&R, P.O. Box 70400, Southwest Station, Washington, D.C. 20024. Telephone: (202) 707–8380. Telefax: (202) 707–8366.

SUPPLEMENTARY INFORMATION:

I. Background

The 1891 Copyright Act initiated a Catalog of Copyright Entries (CCE). The purpose of the catalog was to provide a means for customs officers to prevent importation of pirated copyrighted works. The 1891 Act split responsibility for publishing the catalog between the Librarian of Congress and the Secretary of the Treasury. Copyright Act of 1891, sec. 4, 26 Stat. 1106, 1108 (1891).

The catalog did not provide an efficient means for customs searching; therefore, the Secretary of the Treasury saw little use in continuing publication. The Register of Copyrights, on the other hand, defended the publication in 1904 for a number of reasons. He reasoned that the CCE provided a useful index to copyright businesses and the public without recourse to the Office; a useful reference tool for the staff of the

Copyright Office; a secure record against destruction by fire or other catastrophe; and an official contemporaneous record of the country's intellectual production. He also stated that the cost of the catalog could be defrayed through registration fees. H.R. Doc. No. 420, 58th Cong., 2d Sess. 6 (1904).

The 1909 Copyright Act consolidated responsibility for publication of the catalog in the Copyright Office. Copyright Act of 1909, Pub. L. No. 349, secs. 56, 57, 35 Stat. 1075, 1086. From 1909 to 1936, the Copyright Office regarded the Catalog of Copyright Entries as the primary tool for the public to conduct research on registered copyrights since the public was not encouraged to use Office facilities and Copyright Office staff did not conduct requested searches of any length. During the subsequent years, there was a reduced budget for publication of the catalog; consequently, the number of staff preparing the catalog was reduced, and entries were shortened. However, beginning in 1937, the Office provided a more extended search service and reorganized the records to make searching more efficient. In 1945, a general reorganization of the Copyright Office improved both the search service and the content and timeliness of the catalog. Elizabeth K. Dunne and Joseph W. Rogers, Copyright Law Revision Studies No. 21, 86th Cong., 2d Sess., The Catalog of Copyright Entries, 59–60 (Comm. Print 1960).

Since its inception the catalog has been published as a public service. There have always been relatively few sales, and the catalog has been distributed free to federal depository libraries. These libraries were largely public, university and college libraries which were designated by Members of Congress as being entitled to receive free government documents. Due to the number of such free distributions, costs incurred from publishing the catalog have been considerably larger than revenue from sales to subscribers. In 1959, for example, 37 copies of the Books part of the CCE were sold while 359 were distributed to federal depository libraries, and 85 were given to U.S. government agencies. Id. at 64.

II. The 1976 Copyright Revision Act

As part of the general copyright revision, the Copyright Office conducted 34 studies for Congress on the copyright law; Study No. 21 published in 1960, was devoted to the catalog of copyright entries. Both professional librarians and copyright practitioners commented; commentators generally supported continuation of the publication with some reservations. Considerations favoring continued publication included the fact that a few individuals and organizations found the publication to be highly useful, and alternative avenues for searching copyright information outside of Washington were not readily available. Reservations included acknowledgement that the publications were not widely used by the public at large and publication appeared relatively expensive. In conclusion, most commentators urged a ''flexible'' approach. Elizabeth K. Dunne and Joseph W. Rogers, Copyright Law Revision Studies No. 21, 86th Cong., 2d Sess., The Catalog of Copyright Entries, 77–81 (Comm. Print 1960).

In his report to Congress in 1961 summing up the problems to be considered in drafting a new copyright statute, the Register of Copyrights noted:

> Only a small fraction of the cost of producing the printed catalog is recovered from sales. In 1959, for example, the total cost of assembling, printing, and binding the entire yearly catalog came to about $109,000, while receipts from the year's sales totaled slightly over $4,000. Most of the copies printed are distributed free of charge to libraries and Government agencies.

House Comm. on the Judiciary, 87th Cong., 1st Sess., Report of the Register of Copyrights on the General Revision of the U.S. Copyright Law 144 (Comm. Print 1961).

During the revision process others concurred with the Register that the rigid requirements of the 1909 Act for publication of the catalog should be alleviated and that ''a more flexible authorization to determine the form and frequency of publication of each part of the catalog is highly desirable.'' Supplementary Report of the Register of Copyrights on the General Revision of the U.S. Copyright Law: 1965 Revision Bill, 89th Cong., 1st Sess. 155 (H. Comm. Print 1965). During the early stages of the revision process a far simpler provision intended to encourage a more flexible approach was put forward:

> (a) CATALOG OF COPYRIGHT ENTRIES.—The Register of Copyrights shall compile and publish at periodic intervals catalogs of all copyright registrations. These catalogs shall be divided into parts in accordance with the various classes of works, and the Register has discretion to determine, on the basis of practicability and usefulness, the form and frequency of publication of each particular part.

17 U.S.C. 707(a). This provision remained unchanged throughout the revision process.

Congress emphasized the theme of flexibility, and even mentioned ''electronic devices'' as possibly leading to a better product in the legislative history accompanying the 1976 revision bill. It noted:

> Section 707(a) of the bill retains the present statute's basic requirement that the Register compile and publish catalogs of all copyright registrations at periodic intervals, but provides''discretion to determine, on the basis of practicability and usefulness, for the form and frequency of publication of each particular part''. This provision will in no way diminish the utility or value of the present catalogs, and the flexibility of approach, coupled with use of the new mechanical and electronic devices now becoming available, will avoid waste and result in a better product.

S. Rep. No. 473, 94th Cong., 1st Sess. 154 (1975); H.R. Rep. No. 1476, 94th Cong., 2d Sess. 172 (1976).

III. Copyright Office Budget Constraints

Despite the authorization for continued publication of the catalog in the copyright law, the Office has been unable to meet this responsibility on a timely basis due to increasing budget constraints. In 1982, the Office changed the format of publication of the catalogs from print to microfiche and issued the eight parts of the 1979 edition in that format. Since 1982, delays in issuing the catalog have increased. Currently, the Office is essentially fourteen years behind; it published the 1982 edition in microfiche in 1994 and that has been the last issue to date.

The major cost in producing the CCE is that of creating a master copy from which microfiche copies can be produced. The costs are between $2,500 and $5,000 per master for each part of the catalog. Since each year consists of eight parts, a complete edition would cost approximately between $35,000 and $40,000. Costs for Copyright Office staff who prepare the material for microfilming must also be considered. In 1991, the Office estimated that it would cost over $268,000 to publish the volumes between 1982 and 1991.

The Office has maintained the CCE volumes published so far; some of which are identified in Circular 2, Publications on Copyright, as available for sale. The volume of sales has been quite low. Should the Office resume publication in print or microfiche, as many as 1500 federal depository libraries and government agencies would be entitled to free copies. Although not all of those entitled to receive free copies elect to receive all or any part of the catalog, a heavy printing burden would be imposed on the Office.

IV. On-Line Availability of Copyright Registration Information

Despite the existing lengthy publication delay, there has been little

public comment that the CCE is not delivered on a timely basis, indicating that relatively few people currently rely on the published CCE to secure copyright registration information.

While the Copyright Office has maintained public records since 1870, the information has never been so readily and widely available before. This is due to the fact that in 1994 the Copyright Office inaugurated remote public access via Internet to its computerized database of post 1977 copyright registration and recordation information. Public information on how to use the registration system, including forms and circulars, was included as part of the on-line system.

The registration information and recorded documents which are available over Internet are limited to Copyright Office records produced in machine-readable form from January 1, 1978, to the present. These include the following files: COHM, which contains all original and renewal registrations except serials; COHD, which contains documents; and COHS, which contains serials. Locating information through on-line searches of the record eliminates the need to search individual volumes of the published CCE and is, therefore, far more efficient.

V. Conclusion

While the Copyright Office has historically been assigned the responsibility of creating and maintaining a public record of copyright registration information, the Office has had difficulty in serving the needs of individuals who were unable to come to the Copyright Office. Since the Catalog of Copyright Entries addressed this need, it maintained some level of support within the copyright community. The Office is now providing broad public access on a timely basis via Internet, and there is no longer any reason for maintaining publication of the Catalog of Copyright Entries.

Publication of the catalog has always been quite costly due to the low volume of sales. Moreover, publication of the catalog serves relatively few people since existence of the catalog is not widely known, and only a few hundred copies of each edition of the catalog is distributed. Individuals with access to the Internet, on the other hand, number in the millions; therefore, making copyright registration information available over the Internet is a far more efficient means for publicly disseminating copyright registration information.

The Office has determined that the language of section 707(a) of the Copyright Act is sufficiently flexible to authorize publishing copyright registration information over the Internet. The legislative history of this section emphasizes flexibility and actually mentions ''electronic devices'' as a suitable means for enhancing distribution efficiency. For these reasons, the Copyright Office is discontinuing publication by print or microfiche of the Catalog of Copyright Entries and will meet its responsibilities under 17 U.S.C. 707(a) through publication over Internet. The Office will continue to maintain the volumes of CCE printed so far.

Dated: September 30, 1996.

Marilyn J. Kretsinger,

Acting General Counsel.

[FR Doc. 96–25345 Filed 10–4–96; 8:45 am]

BILLING CODE 1410–30–P

MERIT SYSTEMS PROTECTION BOARD

Sunshine Act Notice

TIME AND DATE: 2:30 p.m., Monday, October 7, 1996.

PLACE: Board Conference Room, Eighth Floor, 1120 Vermont Avenue, N.W., Washington, D.C., 20419.

STATUS: The meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Litigation strategy in the case *Willie Williams* v. *Equal Employment Opportunity Commission,* Docket Number AT–0752–94–0127–I–1 (case caption *Willie Williams* v. *Merit Systems Protection Board,* Docket Number 96–3259 in United States Court of Appeals for the Federal Circuit) and adjudication of *Dexter Neal* v. *Department of Defense,* Docket Number DA–0432–95–0225–I–1.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Matthew Shannon, Counsel to the Clerk of the Board, (202) 653–7200.

Dated: October 2, 1996.

Robert E. Taylor,

Clerk of the Board.

[FR Doc. 96–25718 Filed 10–3–96; 9:30 am]

BILLING CODE 7400–11–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 96–118]

National Environmental Policy Act; X–33 Program: Vehicle Design and Flight Demonstration

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of intent to prepare an environmental impact statement (EIS) and conduct scoping for the development and testing of the X–33 vehicle.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4231 *et seq.*), the Council on Environmental Quality Regulations for Implementing the Procedural Provisions of NEPA (40 CFR Part 1500–1508), and NASA policy and procedures (14 CFR Part 1216 Subpart 1216.3), NASA intends to prepare an EIS for Phase II of the X–33 Program (hereinafter referred to as the ''Program''), which would involve development and demonstration of the X–33 test vehicle. The EIS will address environmental issues associated with the fabrication, assembly, testing, and preparation of the flight operations and landing sites associated with the X–33 technology demonstrator spaceplane. The purpose of the proposed test program is to demonstrate the feasibility of technology which could result in commercially viable Reusable Launch Vehicles (RLV's) with certain aircraft-like operational characteristics. The proposed Phase II of the Program would involve final design, assembly and testing the X–33 vehicle by the year 2000.

Flight operations and landing site alternatives are under consideration to satisfy flight testing requirements. The flight test demonstration program would require short-range, mid-range, and long-range landing sites remote from the flight operations (*i.e.,* vehicle takeoff) site at distances of approximately 160, 640, and 1,360 kilometers (km) (100, 400, and 850 miles (mi)) respectively. The reasonable alternative sites for the proposed flight operations are located within Edwards Air Force Base (EAFB) near Lancaster, California. Alternative landing sites for the flight test activities are being considered in the states of California, Utah, Montana, and Washington.

NASA is the lead agency in the preparation of the EIS. It is anticipated that components of the U.S. Department of Defense, the Bureau of Land Management, and the Federal Aviation Administration will act as cooperating agencies.

DATES: Interested parties are invited to submit comments on or before November 29, 1996, to assure full consideration during the scoping process.

ADDRESSES: Comments should be addressed to Dr. Rebecca C. McCaleb, Director, Environmental Engineering and Management Office, Code AE01,

Marshall Space Flight Centers, Alabama 35812. In addition, comments may be sent to Dr. McCaleb electronically at (X33EIS@msfc.nasa.gov) or by facsimile at 205–544–8259. Information repositories will be maintained at the following locations:

(a) NASA Headquarters, Library, Room 1J20, 300 E Street SW, Washington, DC 20546.

(b) NASA, Marshall Space Flight Center, Library, Building 4200, Huntsville, AL 35812.

(c) Kern County Library, Boron Branch, 27070 Highway 5, Boron, CA 93516.

(d) Kern County Library, Ridgecrest Branch, 131 East Las Flores Street, Ridgecrest, CA 93555.

(e) Los Angeles County Library, Lancaster Branch, 1150 West Avenue J, Lancaster, CA 93524.

(f) Palmdale City Library, 700 East Palmdale Boulevard, Palmdale, CA 93550.

(g) San Bernadino County Library, Barstow Branch, 304 East Buena Vista, Barstow, CA 92311.

(h) Great Falls Public Library, 301 2nd Avenue North, Great Falls, MT 59401.

(i) Moses Lake Library, 418 East 5th Street, Moses Lake, WA 98837.

(j) Dugway Proving Grounds Library, 5124 Kisstler Avenue, Dugway, UT 84022.

(k) Tooele Library, 47 East Vine Street, Tooele, UT 84074.

(l) Salt Lake City Library, 209 East 500 South, Business/Science Department, Salt Lake City, UT 84111.

FOR FURTHER INFORMATION CONTACT; Dr. Dominic A. Amatore, Deputy Director, Public Affairs Office, Code CA01, Marshall Space Flight Center, AL 35812, 205–544–6533. His office will ensure that the appropriate source of information is provided.

SUPPLEMENTARY INFORMATION: The key objectives of the X–33 Design and Flight Demonstration Program include:

—Reduce business and technical risks to privately financed development and operation of a next generation space transportation system through ground and flight tests of a spaceplane technology demonstrator.

—Ensure that the X–33 design and major components are usable and scaleable to a full scale, single-stage-to-orbit (SSTO) RLV

—Demonstrate ''aircraft like'' operations such as reusability and affordability.

—Demonstrate autonomous capability (*i.e.*, vehicle does not have a pilot or onboard flight crew but is controlled by onboard flight management system; vehicle is tracked by telemetry and on systems; and human intervention capability to modify trajectory is maintained at the flight operations site) from takeoff to landing.

—Verify operability and performance in ''real world'' environments.

The X–33 test vehicle is planned as an approximately one-half scale reusable spaceplane. The vehicle would takeoff in a vertical position and use conventional runways to land horizontally. The X–33 vehicle would consist of a lifting body airframe with two cryogenic liquid propellant tanks (liquid hydrogen (LH2) and liquid oxygen (LOX)) placed within the aeroshell, and would use two linear aerospike main engines. Water would be the primary product of the LOX/LH2 combustion. The entire spaceplane (with all fuel tanks and engines) would takeoff and land as a single unit. The flight profile includes takeoff with engine burn until flight speed and altitude objectives are reached; at that point, the engines would cut off.

The flight test plan to meet the Program objectives would involve flights of approximately 160, 640, and 1,360 km (100, 400, and 850 mi). During the landing sequence, the spaceplane would glide to the landing site in an unpowered manner. Flight tests would involve speeds of up to Mach 15 and altitudes up to approximately 75,800 meters (250,000 feet). None of the X–33 tests flights would achieve Earth orbit. Ground operations and servicing (*e.g.*, checkout, refueling, etc.) would be conducted with ''aircraft like'' procedures and systems.

The test flight program is planned to be conducted in three stages, with all takeoffs occurring from the same flight operations site. The three stages would involve the incremental expansion of distance and speed referred to as the ''flight envelope expansion'' which allows the development program to minimize risk while achieving test objectives. The three stage approach would necessitate short-range, mid-range, and long-range landing sites to achieve maximum speeds of Mach 4, 12, and 15, respectively. After each test flight, the X–33 would be ferried back to the takeoff site by a Boeing 747 aircraft in a manner similar to that used for the transport of Space Shuttle orbiters. The test program is currently baselined for a combined total of 15 flights.

Alternatives to be considered for this proposal include, but are not limited to:

—Alternative flight operations (takeoff) sites

—Short-range landing sites

—Mid-range landing sites

—Long-range landing sites

—The ''no action'' alternative which defines the baseline conditions that would prevail in the absence of the X–33 test program.

Three locations within EAFB are the reasonable alternatives being considered for the flight operations site. Reasonable short-range landing sites being considered are Silurian Lake, a dry lake bed, northeast of Barstow, California; and China Lake Naval Weapons Center, near Ridgecrest, California. The baseline alternative for the mid-range landing site is Michael Army Air Field at Dugway proving Grounds, Utah. Reasonable long-range landing sites being considered are Port of Moses Lake, Washington; and Malmstrom Air Force Base near Great Falls, Montana. Analyses conducted to date indicate that other potential flight operations and landing sites are inadequate to meet the requirements of the Program. The ''no action'' alternative (*i.e.*, absence of the X–33 Program) would mean that the RLV Program, as planned, could not proceed, resulting in continued reliance on existing U.S. Government owned or controlled space launch vehicles, such as the Space Shuttle and expendable launch vehicles; and/or space launch vehicles owned and operated by foreign governments.

The EIS will consider the potential environmental impacts associated with the test program and related construction and modification of facilities. An initial assessment of potential environmental impacts indicates that the EIS should focus on sonic booms; potential effects on cultural resources, and threatened and endangered species; on-range and off-range flight test paths; and environmental impacts at the reasonable flight operations and landing site alternatives.

Public scoping meetings will be held at the following dates and locations:

(a) Monday, October 21, 1996; 7:00 p.m. Social Rehabilitative Services Auditorium, Sanders Avenue, Helena, MT 59601.

(b) Tuesday, October 22, 1996: 6:00 p.m. Great Falls High School, 1900 Second Avenue, South, Great Falls, MT 59405.

(c) Thursday, October 24, 1996; 7:00 p.m. Washington State National Guard Armory, 6500 32nd Avenue, N.E., Moses Lake, WA 98837.

(d) Monday, October 28, 1996; 7:00 p.m. Dugway Post Theater, US Army Dugway proving Grounds, Dugway, UT 84022.

(e) Tuesday, October 29, 1996; 7:00 p.m. Tooele Senior Center, 59 East Vine Street, Tooele, UT 84074.

(f) Wednesday, October 30, 1996; 7:00 p.m. Quality Inn Airport, 5575 West Amelia Earhart Drive, Salt Lake City, UT 84116.

(g) Tuesday, November 12, 1996; 7:00 p.m. Best Western Antelope Valley Inn, 44055 North Sierra Highway, Lancaster, CA 93534.

(h) Wednesday, November 13, 1996; 7:00 p.m. Carriage Inn, 901 North China Lake Boulevard, Ridgecrest, CA 93555.

(i) Thursday, November 14, 1996; 7:00 p.m. West Boron Elementary School, 12300 Del Oro, Boron, CA 93516.

(j) Saturday, November 16, 1996; 10:00 a.m. Holiday Inn, 1511 East Main Street, Barstow, CA 92311.

Written public input and comments on environmental impacts associated with the proposed Program, including, but not limited to, flight operations and landing site options, as well as related environmental concerns, are hereby solicited.

Dated: October 1, 1996.

Benita A. Cooper,

Associate Administrator for Management Systems and Facilities.

[FR Doc. 96–25643 Filed 10–4–96; 8:45 am]

BILLING CODE 7510–10–M

[Notice 96–119]

NASA Advisory Council; 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 meeting of the NASA Advisory Council.

DATES: October 31, 1996, 9:00 a.m. to 2:30 p.m.; and November 1, 1996, 8:30 a.m. to 3:00 p.m..

ADDRESSES: National Aeronautics and Space Administration, Room 9H40, 300 E Street, SW., Washington, DC 20546–0001.

FOR FURTHER INFORMATION CONTACT: Ms. Anne L. Accola, Code Z, National Aeronautics and Space Administration, Washington, DC 20546–0001, 202/358–0682.

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:

—National Space Policy
—Questions to Focus NASA's Mission
—Update on Activities at NASA
—Advanced Technology Reorganization
—Report of Systems Concepts and Analysis Field Trip
—Space Debris
—Exobiology Responsibility
—Status of Mars Exploration Planning
—Committee/Task Force Reports
—Discussion of Findings and Recommendations

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Visitors will be requested to sign a visitor's register.

Dated: September 30, 1996.

Leslie M. Nolan,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 96–25644 Filed 10–4–96; 8:45 am]

BILLING CODE 7510–01–M

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Records Schedules; Availability and Requests for Comments

AGENCY: National Archives and Records Administration, Office of Records Administration.

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Records schedules identify records of sufficient value to warrant preservation in the National Archives of the United States. Schedules also authorize agencies after a specified period to dispose of records lacking administrative, legal, research, or other value. Notice is published for records schedules that (1) propose the destruction of records not previously authorized for disposal, or (2) reduce the retention period for records already authorized for disposal. NARA invites public comments on such schedules, as required by 44 U.S.C. 3303a(a).

DATES: Request for copies must be received in writing on or before November 21, 1996. Once the appraisal of the records is completed, NARA will send a copy of the schedule. The requester will be given 30 days to submit comments.

ADDRESSES: Address requests for single copies of schedules identified in this notice to the Records Appraisal and Disposition Division (NIR), National Archives and Records Administration, College Park, MD 20740. Requesters must cite the control number assigned to each schedule when requesting a copy. The control number appears in the parentheses immediately after the name of the requesting agency.

SUPPLEMENTARY INFORMATION: Each year U.S. Government agencies create billions of records on paper, film, magnetic tape, and other media. In order to control this accumulation, agency records managers prepare records schedules specifying when the agency no longer needs the records and what happens to the records after this period. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. These comprehensive schedules provide for the eventual transfer to the National Archives of historically valuable records and authorize the disposal of all other records. Most schedules, however, cover records of only one office or program or a few series of records, and many are updates of previously approved schedules. Such schedules also may include records that are designated for permanent retention.

Destruction of records requires the approval of the Archivist of the United States. This approval is granted after a thorough study of the records that takes into account their administrative use by the agency of origin, the rights of the Government and of private persons directly affected by the Government's activities, and historical or other value.

This public notice identifies the Federal agencies and their subdivisions requesting disposition authority, includes the control number assigned to each schedule, and briefly describes the records proposed for disposal. The records schedule contains additional information about the records and their disposition. Further information about the disposition process will be furnished to each requester.

Schedules Pending

1. Department of State, Bureau of Politico-Military Affairs (N1–59–96–18). Routine, facilitative, and duplicative records of the Nuclear Risk Reduction Center.

2. Department of Education (N1–441–96–2). Citizen correspondence, graphics design records, training films, and other records maintained by the Office of Public Affairs.

3. Department of Housing and Urban Development (N1–207–96–5). Routine and administrative reports and working files for the Multifamily Tenant Characteristics System, (data files and documentation will be preserved).

4. Department of Housing and Urban Development (N1–207–96–6). Reports, data, tracking files and documentation for subsystems of the Homeless Assistance Management Information

system, (application history system data and documentation will be preserved).

5. Department of Justice (N1–60–96–5). Records maintained by the Legal Support Unit, Criminal Division, relating to requests for authorization to conduct grand jury proceedings and take other legal actions.

6. Department of Justice (N1–60–96–7). Documents submitted voluntarily or under subpoena to the Criminal Division that are not used in litigating the case for which they were obtained.

7. Department of Labor (N1–174–96–6). Revisions to the comprehensive schedule for the Office of Public Affairs.

8. Department of the Treasury, Bureau of Alcohol, Tobacco, and Firearms (N1–436–93–1). Ad hoc management reports generated by the National Firearms Registration and Transfer Record, (the master file for this system is designated for preservation).

9. Department of the Treasury, Bureau of Alcohol, Tobacco, and Firearms (N1–436–96–7). Firearms Technology Branch technical determinations.

10. Federal Deposit Insurance Corporation (N1–034–95–2). Records relating to the resolution of failed financial institutions.

Dated: September 27, 1996.

James W. Moore,

Assistant Archivist for Records Administration.

[FR Doc. 96–25567 Filed 10–4–96; 8:45 am]

BILLING CODE 7515–01–M

NATIONAL SCIENCE FOUNDATION

Advisory Panel for Cell Biology; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub.L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Advisory Panel for Cell Biology (1136)—(Panel A).

Date and Time: October 23–25, 1996, 8:30 a.m. to 6:00 p.m.

Place: Room 380, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Persons: Dr. Barbara Zain, Program Director for the Cell Biology Program, National Science Foundation, Room 655 South, Arlington, VA 22230. Telephone: 703/306–1442.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate research proposals submitted to the Signal Transduction Program as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: October 1, 1996.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 96–25619 Filed 10–4–96; 8:45 am]

BILLING CODE 7555–01–M

NEIGHBORHOOD REINVESTMENT CORPORATION

Sunshine Act Meeting; Regular Meeting of the Board of Directors

TIME & DATE: 2:00 P.M., Thursday, October 17, 1996.

PLACE: Neighborhood Reinvestment Corporation, 1325 G Street, N.W., Suite 800, Board Room, Washington, D.C. 20005.

STATUS: Open.

CONTACT PERSON FOR MORE INFORMATION: Jeffrey T. Bryson, General Counsel/Secretary, 202/376–2441.

AGENDA:

I. Call to Order
II. Approval of Minutes: July 31, 1996, Regular Meeting
III. Treasurer's Report
IV. Executive Director's Quarterly Management Report
V. Adjourn

Jeffery T. Bryson,

General Counsel/Secretary.

[FR Doc. 96–25819 Filed 10–3–96; 3:34 pm]

BILLING CODE 7570–01–M

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: U. S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to OMB and solicitation of public comment.

SUMMARY: The NRC is preparing a submittal to OMB for review of continued approval of information collections under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. The title of the information collection: 10 CFR 35.32 and 35.33 ''Quality Management Program and Misadministrations''.

2. Current OMB approval number: 3150–0171.

3. How often the collection is required: For quality management program (QMP):

Reporting: One time submittal of a quality management program (QMP) for each existing and new licensee, when the QMP is modified, or when new modalities (uses) are added to an existing license.

Ten Agreement States, who should have adopted the rule by January 1995, have not done so. Therefore, this estimate includes the one-time burden for the development of QMPs by these ten Agreement State licensees.

Recordkeeping: Records of written directives, administered dose or dosage, annual review, and recordable events, for 3 years.

For Misadministrations:

Reporting: Whenever a misadministration occurs.

Recordkeeping: Records of misadministrations for 5 years.

4. Who is required or asked to report: NRC Part 35 licensees who use byproduct material in limited diagnostic and therapeutic ranges and similar type of licensees regulated by Agreement States.

5. The number of respondents: 6300 licensees.

6. The number of hours needed annually to complete the requirement or request: 34,743 hours for applicable licensees (24,400 hrs/yr for reporting and 10,343 hrs/yr for recordkeeping).

7. Abstract: In the medical use of byproduct material, there have been instances where byproduct material was not administered as intended or was administered to a wrong individual, which resulted in unnecessary exposures or inadequate diagnostic or therapeutic procedures. The most frequent causes of these incidents were: insufficient supervision, deficient procedures, failure to follow procedures, and inattention to detail. In an effort to reduce the frequency of such events, the NRC requires licensees to implement a quality management program (§ 35.32) to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by an authorized user physician.

Collection of this information enables the NRC to ascertain whether misadministrations are properly identified, evaluated, and investigated by the licensee and that corrective action is taken. Additionally, NRC has a responsibility to inform the medical community of generic issues identified

in the NRC review of misadministrations.

Submit, by December 6, 1996, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the draft supporting statement may be viewed free of charge at the NRC Public Document Room, 2120 L Street NW, (lower level), Washington, DC. Members of the public who are in the Washington, DC, area can access this document via modem on the Public Document Room Bulletin Board (NRC's Advanced Copy Document Library), NRC subsystem at FedWorld, 703–321–3339. Members of the public who are located outside of the Washington, DC, area can dial FedWorld, 1–800–303–9672, or use the FedWorld Internet address: fedworld.gov (Telnet). The document will be available on the bulletin board for 30 days after the signature date of this notice. If assistance is needed in accessing the document, please contact the FedWorld help desk at 703–487–4608.

Additional assistance in locating the document is available from the NRC Public Document Room, nationally at 1–800–397–4209, or within the Washington, DC, area at 202–634–3273.

Comments and questions about the information collection requirements may be directed to the NRC Clearance Officer, Brenda Jo. Shelton, U.S. Nuclear Regulatory Commission, T–6 F33, Washington, DC, 20555–0001, or by telephone at (301) 415–7233, or by Internet electronic mail at BJS1@NRC.GOV.

Dated at Rockville, Maryland, this 18th day of October, 1996.

For the Nuclear Regulatory Commission.

Gerald F. Cranford,

Designated Senior Official for Information Resources Management.

[FR Doc. 96–25627 Filed 10–04–96; 8:45 am]

BILLING CODE 7590–01–P

[Docket Nos. 50–424 and 50–425]

Georgia Power Company, et al.; Notice of Issuance of Amendments to Facility Operating Licenses

The U.S. Nuclear Regulatory Commission (Commission) has issued Amendment No. 96 to Facility Operating License No. NPF–68 and Amendment No. 74 to Facility Operating License No. NPF–81 issued to Georgia Power Company, et al. (the licensee), which revised the Technical Specifications and associated Bases for operation of the Vogtle Electric Generating Plant, Units 1 and 2, located in Burke County, Georgia.

The amendments are effective as of the date of issuance and shall be implemented within 150 days from the date of issuance. Implementation shall include the relocation of Technical Specification requirements to the appropriate licensee-controlled document as identified in the licensee's application dated May 1, 1995, as supplemented by letters dated August 3 and 9, September 22, November 20, and December 21, 1995, January 26 and 30, February 19 and 29, March 5 and 12, May 6, June 17, August 23, and September 13, 1996, and reviewed in the staff's Safety Evaluation dated

The amendments replaced, in its entirety, the current Technical Specifications and associated Bases with a set based on NUREG–1431, ''Standard Technical Specifications, Westinghouse Plants,'' Revision 1, dated April 1995.

There are three specific items in the licensee's application that are still being reviewed by the staff. Two of these items are the allowed outage time (AOT) for the emergency diesel generators (EDGs) and the AOT for the containment spray system. In accordance with supplements to the initial application, these two items are being addressed in the license amendments by retaining the provisions of the licensee's current licensing basis. New licensing actions are being initiated as a means for continuing the staff evaluation of the AOT proposals. Appropriate license amendments will be issued when those reviews are completed.

The third item concerns the staff evaluation of the licensing basis for containment isolation valves in closed systems. The licensee's current licensing basis is being retained pending the resolution of an unresolved inspection item. Any changes needed to Technical Specification 3.6.3 as a result of that review will be addressed in a future licensing action. The licensee will be kept informed of the status of that review in separate correspondence.

All other issues in the licensee's application for Technical Specification conversion are resolved in the license amendments.

The application for the amendments, dated May 1, 1995, as supplemented by letters dated August 3 and 9, September 22, November 20, and December 21, 1995, January 26 and 30, February 19 and 29, March 5 and 12, May 6, June 17, August 23, and September 13, 1996, complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendments.

Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Opportunity for a Hearing in connection with this action was published in the Federal Register on September 7, 1995 (60 FR 46633) and on January 10, 1996 (61 FR 734). No request for a hearing or petition for leave to intervene was filed following these notice.

The Commission has prepared an Environmental Assessment related to the action and has determined not to prepare an environmental impact statement. Based upon the environmental assessment, the Commission has concluded that the issuance of the amendment will not have a significant effect on the quality of the human environment (61 FR 8308).

For further details with respect to the action see (1) the application for amendments dated May 1, 1995, as supplemented by letters dated August 3 and 9, September 22, November 20, and December 21, 1995, January 26 and 30, February 19 and 29, March 5 and 12, May 6, June 17, August 23, and September 13, 1996, (2) Amendment No. 94 to License No. NPF–68 and Amendment No. 72 to License No. NPF–81, (3) the Commission's related Safety Evaluation dated September 25, 1996, and (4) the Commission's Environmental Assessment dated February 27, 1996.

All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC, and at the local public document room located at the Burke County Library, 412 Fourth Street, Waynesboro, Georgia.

Dated at Rockville, Maryland, this 25th day of September 1996.

For the Nuclear Regulatory Commission.

Louis L. Wheeler,

Senior Project Manager, Project Directorate II–2, Division of Reactor Projects - I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 96–25626 Filed 10–4–96; 8:45 am]

BILLING CODE 7590–01–P

[Docket No. 50–305]

Wisconsin Public Service Company, Wisconsin Power and Light Company and Madison Gas and Electric Company; Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License Nos. DPR–43 issued to Wisconsin Public Service Corporation, Wisconsin Power and Light Company, and Madison Gas and Electric Company (the licensee), for operation of the Kewaunee Nuclear Power Plant, located in Kewaunee County, Wisconsin.

The proposed amendment would change Technical Specification (TS) requirements related to the low temperature overpressure protection (LTOP) system. Specifically, the LTOP curve would be modified to define 10 CFR Part 50, Appendix G pressure temperature limitations for LTOP evaluation through the end of operating cycle (EOC) 33. In addition, the LTOP enabling temperature and the temperature required for starting a reactor coolant pump would be changed consistent with the design basis for the LTOP system. Finally, the TS bases would be changed consistent with the changes described above.

In a letter dated September 27, 1996, the licensee requested that this amendment application be treated exigently. The current LTOP curve is applicable through EOC 21 or 18.40 effective full-power years (EFPY). The startup for cycle 22 is scheduled for October 22, 1996. Due to time constraints, sufficient time is not available to permit the customary public notice in advance of this action. This proposed amendment supersedes a previously submitted proposed amendment on this subject dated April 30, 1996, which was published in the Federal Register on May 22, 1996 (61 FR 25714). The new submittal was necessary in order to address NRC concerns with the original submittal.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

Pursuant to 10 CFR 50.91(a)(6) for amendments to be granted under exigent circumstances, the NRC staff must determine that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The proposed change was reviewed in accordance with the provisions of 10 CFR 50.92 to show no significant hazards exist. The proposed change will not:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated.

The LTOP setpoint, revised enabling temperature, and revised P/T [pressure/temperature] limits reflected in proposed Figure TS 3.1–4 ensure that the Appendix G pressure/temperature limits are not exceeded, and therefore, help ensure that RCS [reactor coolant system] integrity is maintained. The changes do not modify the reactor coolant system pressure boundary, nor make any physical changes to the facility design, material, construction standards, or setpoints. The LTOP valve setpoint remains at ≤ 500 psig. The LTOP enabling temperature based on Figure TS 3.1–4 is 355 °F and is consistent with BTP RSB 5–2 guidance of RT_{NDT} + 90 °F. The revised enabling temperature is greater than the 338 °F value in the current TS. A higher enabling temperature ensures that the LTOP system is available for the prevention of non-ductile failure over a larger operating window. The probability of a LTOP event occurring is independent of the pressure-temperature limits for the RCS pressure boundary and enabling temperature. Therefore, the probability of a LTOP event is not increased.

The calculation of pressure temperature limits in accordance with approved regulatory methods provides assurance that reactor pressure vessel fracture toughness requirements are met and the integrity of the RCS pressure boundary is maintained. Similar methodology was used in calculations to support approved amendment 120 to the Kewaunee Technical Specifications dated April 26, 1995. The material property bases, including chemistry factor and initial reference temperature for the unirradiated material (RT_{NDT}), and margin terms, used for this PA are more conservative than that used in the current TS.

The PT limits reflected in proposed Figure TS 3.1–4 are based on the following criteria:

(a) An initial RT_{NDT} value of –56 °F. Drop weight testing of Kewaunee surveillance material was performed by the Westinghouse Electric Corporation and documented in WCAP 14042, Revision 1, dated January 1995 with a resultant initial RT_{NDT} of –50 °F. Testing of sister plant surveillance material resulted in an initial RT_{NDT} of –30 °F. The mean value for all Linde 1092 weld heats in –50.7 °F. Therefore, use of the generic value of –56 °F (for welds made with Linde 1092 flux) with a larger margin term was deemed more conservative and acceptable for this evaluation.

(b) Paragraph (c)(2)(ii)(A) of 10 CFR 50.61. Paragraph (c)(2)(ii)(A) of 10 CFR 50.61 requires that licensees determine a material-specific value of chemistry factor when the surveillance data is deemed credible according to the criteria of paragraph (c)(2)(I) of 10 CFR 50.61. Reference 3 documents WPSC's evaluation which concludes that the KNPP surveillance capsule data satisfy the credibility criteria. The calculated material-specific chemistry factor value is 190.6 °F (based on KNPP surveillance capsule data from capsules V, R, P, and S). Adjustment of this chemistry factor has been accomplished by multiplying by 1.18, the ratio of the best estimate chemistry factor for heat IP3571 to the chemistry factor for the Kewaunee surveillance weld. This results in a chemistry factor value of 224.9 °F.

(c) Neutron fluence (E greater than 1 MeV) projections through [the] end of operating cycle 33. The use of predicted fluence values through the end of operating cycle 33 is appropriately considered within the calculations in accordance with standard industry methodology previously docketed under WCAP 13227 and WCAP 14279. The neutron exposure projections utilized for calculation of the reference temperature were multiplied by a factor of 1.11 to adjust for biases observed between cycle specific calculations and the results of neutron dosimetry for the four surveillance capsules removed from the KNPP reactor. The factor of 1.11 was derived by taking the average of the measured to calculation (M/C) flux ratios obtained from the dosimetry results of capsules V, R, P, and S removed from the KNPP reactor vessel. The resulting effect of using predicted fluence values through the end of cycle 33 instead of cycle 21 is to require the [plant to evaluate LTOP transients to more limiting requirements].

Additional conservatism from a more conservative material property basis and higher projected fluence values is readily illustrated by the increase in magnitude of $EOC_{NDT1/4T}$ from 212.94 °F (derived from the material property basis used in the current TS) to 264.46oF used for this PA. The proposed PT limits are shifted to a lower pressure and higher temperature, which is more conservative.

The changes do not adversely affect the integrity of the RCS such that its function in the control of radiological consequences is affected. In addition, the changes do not affect any fission barrier. The changes do not degrade or prevent the response of the LTOP relief valve or other safety-related systems to

previously evaluated accidents. In addition, the changes do not alter any assumption previously made in the radiological consequences evaluations nor affect the mitigation of the radiological consequences of an accident previously evaluated. Therefore, the consequences of an accident previously evaluated will not be increased.

Thus, operation of KNPP in accordance with the PA does not involve a significant increase in the probability or consequences of any accident previously evaluated.

2. Create the possibility of a new or different type of accident from an accident previously evaluated.

The enabling temperature and Appendix G pressure temperature limitations were prepared using methods derived from the ASME Boiler and Pressure Vessel Code and the criteria set forth in NRC Regulatory Standard Review Plan 5.3.2. The changes do not cause the initiation of any accident nor create any new credible limiting failure for safety-related systems and components. The changes do not result in any event previously deemed incredible being made credible. As such, it does not create the possibility of an accident different than previously evaluated.

The changes do not have any adverse effect on the ability of the safety-related systems to perform their intended safety functions. Since the enabling temperature is higher, the LTOP system is available for prevention of non-ductile failure over a wide operating window. The new LTOP operating window (i.e., less than or equal to 355 °F) is within the existing band for the residual heat removal system; operating procedures allow the LTOP system to be placed into service at less than 400 °F. The proposed changes do not make physical changes to the plant or create new failure modes. Therefore, it will not create the possibility of a malfunction of equipment important to safety different than previously evaluated. Thus, the PA does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The use of Paragraph (c)(2)(ii)(A) of 10 CFR 50.61, chemistry factor ratio of 1.18, initial reference temperature of –56 °F, and fluence values through EOC [end of cycle] 33 does not modify the reactor coolant system pressure boundary, nor make any physical changes to the LTOP setpoint or system design. Proposed Figure TS 3.1–4 was prepared in accordance with regulatory requirements and requires evaluation of LTOP events to the more conservative material property basis and more limiting requirements of neutron exposure projections of 33.41 EFPY instead of 18.40 EFPY.

Therefore, the PA does not create the possibility of a new or different type of accident from any accident previously evaluated.

3. Involve a significant reduction in the margin of safety.

The Appendix G pressure temperature limitations were prepared using methods derived from the ASME Boiler and Pressure Vessel Code and the criteria set forth in NRC Regulatory Standard Review Plan 5.3.2. These documents along with the calculational limitations specified in 10 CFR 50.61 are an acceptable method for implementing the requirements of 10 CFR 50 Appendices G and H. Inherent conservatism in the P/T limits resulting from these documents include:

a. An assumed defect in the reactor vessel wall with a depth equal to ¼ of the thickness of the vessel wall (¼T) and a length equal to 1½ times the thickness of the vessel wall.

b. Assumed reference flaw oriented in both longitudinal and circumferential directions and limiting material property. At KNPP, the only weld in the core region is oriented in the circumferential direction.

c. A factor of safety of 2 is applied to the membrane stress intensity factor.

d. The limiting toughness is based upon a reference value (K_{IR}) which is a lower bound on the dynamic crack initiation or arrest toughness.

e. A 2-sigma margin term is applied in determining the adjusted reference temperature (ART) that is used to calculate the limiting toughness.

Similar methodology was used in calculations to support approved amendment 120 dated April 26, 1995. Beyond the conservatism described above, WPSC [Wisconsin Public Service Corporation] has incorporated the following additional margin in preparing this PA:

a. The reactor coolant pump starting restrictions of TS 3.1.a.1.c reflect the more limiting LTOP enabling temperature of 355 °F consistent with the design basis for the LTOP system.

b. The LTOP enabling temperature based on Figure TS 3.1–4 is 355 °F and is more conservative than the 338oF value in the current TS.

c. The calculated material-specific chemistry factor value of 190.6oF (based upon KNPP surveillance capsule data from capsules V, R, P, and S) has been multiplied by 1.18 yielding an adjusted chemistry factor value of 224.9oF to account for chemical composition differences between the best estimate value for weld heat IP3571 and the Kewaunee surveillance weld material. d. The neutron exposure projections were multiplied by a factor of 1.11 to adjust for biases observed between cycle specific calculations and the results of neutron dosimetry for the four surveillance capsules removed from the KNPP reactor. The factor of 1.11 was derived by taking the average of the measured to calculation (M/C) flux ratios obtained from the dosimetry results of capsules V, R, P, and S removed from the KNPP reactor vessel. Additional conservatisms beyond that described above but not used in development of the proposed TS and Figure include: (a) A 2 inch diameter spring loaded safety valve set at 480 psig located in the LTOP system. At 500 psig, the LTOP relief valve setpoint, the relieving capacity of this smaller valve is 230 gpm. (b) The actual LTOP relief valve capacity is at least 10% greater than the capacity used in the design and setpoint analyses. This is in accordance with the requirements of Section III NC–7000. (c) Assumptions in the overpressure transient analyses are conservative relative to the actual Kewaunee reactor coolant system (RCS) and operating practices:

1. The RCS was assumed to be rigid with respect to metal expansion.

2. No credit was taken for the shrinkage effect caused by low temperature safety injection water added to higher temperature reactor coolant.

3. No credit was taken for the reduction in reactor coolant bulk modulus at RCS temperatures above 100°F (constant bulk modulus at all RCS temperatures).

4. The entire volume of water of the steam generator secondary was assumed available for heat transfer to the primary. In reality, the liquid immediately adjacent and above the tube bundle would be the primary source of energy in the transient.

5. The overall steam generator heat transfer coefficient, U, was assumed to be the free convective heat transfer coefficient of the secondary, h_{sec}. The forced convective heat transfer coefficient of the primary, h_{pri} and the tube metal resistance have been ignored thus resulting in a conservative (high) coefficient.

6. The reactor coolant pump start time assumed in the heat input analysis was 9–10 seconds; whereas, the Kewaunee pump startup time is 25–30 seconds.

An alternative methodology to the safety margins required by Appendix G to 10 CFR Part 50 has been developed by the ASME Working Group on Operating Plant Criteria. This methodology is contained in ASME Code Case N–514. The Code Case N–514 provides criteria to determine pressure limits during LTOP events that avoid certain unnecessary operational restrictions, provide adequate margins against failure of the reactor pressure vessel, and reduce the potential for unnecessary activation of the relief valve used for LTOP. Specifically, the ASME Code Case N–514 allows determination of the setpoint for LTOP events such that the maximum pressure in the vessel would not exceed 110% of the P/T limits of the existing ASME Appendix G; and redefines the enabling temperature at a coolant temperature less than 200°F or a reactor vessel metal temperature less than RT_{NDT} + 50°F, whichever is greater. Code Case N–514, ''Low Temperature Overpressure Protection,'' has been approved by the ASME Code Committee but not yet approved for use in Regulatory Guide 1.147. The content of this code case has been incorporated into Appendix G of Section XI of the ASME Code and published in the 1993 Addenda to Section XI. It is expected that next revision of 10 CFR 50.55a will endorse the 1993 Addenda and Appendix G of Section XI. As stated above, this PA utilizes Appendix G limits and an enabling temperature corresponding to a reactor vessel metal temperature less than RT_{NDT} + 90°F, which is more conservative than the alternative methodology contained in Code Case N–514.

The revised calculations meet the NRC acceptance criteria for the LTOP setpoint and system design as described in NRC Safety Evaluation Report (SER) dated September 6, 1985 which concluded that ''the spectrum of postulated pressure transients would be mitigated * * * such that the temperature pressure limits of Appendix G to 10 CFR 50 are maintained.''

Use of the methodology set forth in the ASME Boiler and Pressure Vessel Code, NRC

Regulatory Standard Review Plan 5.3.2, 10 CFR 50.61, and 10 CFR 50 Appendices G and H with the above additional margins ensures that proper limits and safety factors are maintained. Thus, the PA does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 15 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 15-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in preventing startup of the facility, the Commission may issue the license amendment before the expiration of the 15-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the Federal Register a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this Federal Register notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By November 6, 1996, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the University of Wisconsin, Cofrin Library, 2420 Nicolet Drive, Green Bay, Wisconsin 54311–7001. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1–(800) 248–5100 (in Missouri

1–(800) 342–6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to Gail H. Marcus: petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this Federal Register notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Bradley D. Jackson, Esq., Foley and Lardner, P. O. Box 1497, Madison, Wisconsin 53701–1497, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated September 27, 1996, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the University of Wisconsin, Cofrin Library, 2420 Nicolet Drive, Green Bay, Wisconsin 54311–7001.

Dated at Rockville, Maryland, this 2nd day of October 1996.

For The Nuclear Regulatory Commission.

Richard J. Laufer,

Project Manager, Project Directorate III–3, Division of Reactor Projects—III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 96–25625 Filed 10–4–96; 8:45 am]

BILLING CODE 7590–01–P

Strategic Assessment and Rebaselining Stakeholders Public Meetings

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The Nuclear Regulatory Commission is requesting public comment on the second phase of a critical evaluation known as strategic assessment and rebaselining initiative. The NRC is utilizing various media and conducting three public conferences in order to reach as many stakeholders as possible. The objectives of these public meetings are to give the public an opportunity to meet with agency representatives and comment on 16 issue papers the Commission has under active consideration.

This effort was initiated in September 1995, and is being completed in four phases with the goal of finalizing a strategic plan in early CY 1997. The development and implementation of this strategic plan will meet the requirements of the Government Performance and Results Act (GPRA) of 1993.

The effort is presently in the latter portion of the second phase where the Commission is considering a variety of options for addressing key strategic issues facing the NRC as it prepares to move into the 21st century. The NRC will be seeking the views and comments of its stakeholders—Federal entities (Administration/OMB, Congress, and other agencies), NRC employees and their representatives, Agreement States, non-Agreement States, compliers (e.g., licensees, employees of licensees, industry groups), public interest groups, and the general public—as part of the decision-making process. The stakeholder involvement effort began in mid-September and concludes on November 15, 1996. The Commission will consider stakeholder comments before making final decisions on the key strategic issues.

During the week of September 16, 1996, the issue papers and other documents dealing with the strategic assessment were made available to the public. Copies of these documents as well as registration and general information on the public meetings can be obtained electronically from the NRC's Home Page on the World Wide Web (Internet address http://www.nrc.gov) and FedWorld at 1–800–303–9672. Paper copies are available by calling NRC's Public Document Room at 1–800–397–4209.

To help understand their viewpoints, stakeholders are asked to focus on the following in responding to the NRC:

1. What, if any, important considerations may have been omitted from the issue papers?

2. How accurate are the NRC's assumptions and projections for internal and external factors discussed in the issue papers?

3. Do the Commission's preliminary views associated with each issue paper respond to the current environment and challenges?

4. Additionally, the Commission is seeking comments on specific questions identified in the ''Preliminary Commission View'' section of each issue paper.

In Phase I, a steering committee comprised of senior agency managers, working with an outside consultant, reviewed the NRC's activities in order to understand where the NRC is today, and what needs to be considered in providing options for responding to change. Some of the key objectives identified by the steering committee were: establish a strategic framework under which the NRC will continue to meet its primary responsibility of protecting public health and safety and the environment; provide a sound and well-rounded foundation for the NRC's direction and decision-making for the rest of this decade and into the next century; ensure that the Commission, its staff, Congress, other Government agencies, and the public have a common understanding of what the NRC's strategic goals are; and establish agency performance measures to determine the extent to which strategic or tactical objectives are being achieved.

The NRC will hold three public meetings to discuss the issue papers and to obtain comments from stakeholders. The conference dates and locations are:

DATES: October 24–25, Washington, DC—Washington Hilton; October 31–November 1, Colorado Springs, CO—Sheraton Hotel; November 7–8, Chicago, IL—the Ramada O'Hare.

ADDRESSES: The Washington Hilton and Towers; 1919 Connecticut Avenue NW., Washington, DC 20009 (Tel: 202–483–3000; Fax: 202–265–8221); The Sheraton Colorado Springs Hotel; 2886 South Circle Drive; Colorado Springs, CO 80906 (Tel: 719–576–5900; Fax: 719–576–7695); The Ramada Hotel—O'Hare; 6600 N. Mannheim Road; Rosemont, IL 60018 (Tel: 847–827–5131; Fax: 847–827–5659).

Registration Information

Additional information on the agenda, times, and locations of the public meetings is available via Internet as indicated above. Sleeping rooms have been reserved at a special conference rate at each of the hotels. Those planning to attend the meeting(s) should make their own hotel reservations by telephone using a major credit card, and identifying themselves as an attendee of the NRC Public Meeting. There will be no charge for attending these public meetings, and registration will be held onsite.

Miscellaneous questions about registration should be directed to: Anna May Haycraft, U.S. Nuclear Regulatory Commission; Internet: AMH@NRC.gov or Phone: 301–415–3075.

Dated in Rockville, Maryland this 2nd day of October 1996.

For the Nuclear Regulatory Commission.

John W. Craig,

Coordinator, Strategic Assessment Coordination Task Group.

[FR Doc. 96–25742 Filed 10–4–96; 8:45 am]

BILLING CODE 7590–01–P

Sunshine Act Meeting

DATE: Wednesday, October 2, 1996.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

MATTERS TO BE CONSIDERED:

Wednesday, October 9

11:30 a.m.—Affirmation Session (Public Meeting)

a. Final Rulemaking—Revision to 10 CFR Part 20, Constraint for Airborne Radioactive Effluents to the Environment form NRC Licensees Other than Power Reactors and Agreement State Licensees; and Revision of the General Statement of Policy and Procedures for NRC Enforcement Actions (tentative)

(Contact: Andrew Bates, 301–415–1963)

* The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: Bill Hill (301) 415–1661.

* * * * *

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to it, please contact the Office of the Secretary, Attn: Operations Branch, Washington, D.C. 20555 (301–415–1963).

In addition, distribution of this meeting notice over the internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to wmh@nrc.gov or dkw@nrc.gov.

* * * * *

Dated: October 2, 1996.

William M. Hill, Jr.,

SECY Tracking Officer, Office of the Secretary.

[FR Doc. 96–25735 Filed 10–3–96; 11:43 am]

BILLING CODE 7590–01–M

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extensions:		
Form 6–K	SEC File No. 270–107	OMB Control No. 3235–0116
Form F–7	SEC File No. 270–331	OMB Control No. 3235–0383
Form F–8	SEC File No. 270–332	OMB Control No. 3235–0378
Form F–X	SEC File No. 270–336	OMB Control No. 3235–0379
Sch. 13E–4F	SEC File No. 270–340	OMB Control No. 3235–0375
Sch. 14D–1F	SEC File No. 270–338	OMB Control No. 3235–0376
Sch. 14D–9F	SEC File No. 270–339	OMB Control No. 3235–0382

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the Securities and Exchange Commission (''Commission'') is publishing the following summaries of collections for public comment.

Form 6–K elicits material information from issuers of publicly-traded securities promptly after the occurrence of specified or other important corporate events so that investors have current information upon which to base investment decisions. Form 6–K is filed by approximately 990 respondents annually for a total burden of 7920 hours.

Form F–7 may be used to register securities offered for cash upon the exercise of rights granted to existing shareholders of the registrant. Form F–7 is filed by approximately 10 respondents annually for a total burden of 20 hours.

Form F–8 may be used to register certain Canadian issuers in exchange offers or business combinations. Form F–8 is filed by approximately 5 respondents annually for a total burden of 10 hours.

Form F–X is used to appoint an agent for service of process by Canadian issuers registering securities on Form F–7, Form F–8, Form F–9 or Form F–10, or filing periodic reports on Form 40–F. Form F–X is filed by approximately 50 respondents annually for a total burden of 100 hours.

Schedule 13E–4F may be used by any issuer incorporated or organized under the laws of Canada making a tender offer for the issuer's own securities, where less than 20% of the class of such issuer's securities that is the subject of the tender offer is held of record by United States residents. Schedule 13E–4F is filed by approximately 3 respondents annually for a total burden of 6 hours.

Schedule 14D–1F may be used by any person making a cash tender or exchange offer for securities of any issuer incorporated or organized under the laws of Canada that is a foreign private issuer, where less than 40% of the outstanding class of such issuer's securities that is the subject of the offer is held by United States holders. Schedule 14D–1F is filed by approximately 5 respondents annually for a total burden of 10 hours.

Schedule 14D–9F is used by any issuer incorporated or organized under the laws of Canada, or by any director or officer of such issuer, where the issuer is the subject of a tender offer for a class of its securities filed on Schedule 14D–1F. Schedule 14D–9F is filed by approximately 5 respondents annually for a total burden of 10 hours.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use

of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Direct your written comments to Michael E. Bartell, Associate Executive Director, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549.

Dated: September 19, 1996.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–25621 Filed 10–4–96; 8:45 am]

BILLING CODE 8010–01–M

[Investment Company Act Release No. 22255; 812–10292]

PaineWebber America Fund, et al.; Notice of Application

September 30, 1996.

AGENCY: Securities and Exchange Commission (''SEC'').

ACTION: Notice of application for an order under the Investment Company Act of 1940 (the ''Act'').

APPLICANTS: PaineWebber America Fund; PaineWebber Cashfund, Inc.; PaineWebber Investment Series; PaineWebber Managed Assets Trust; PaineWebber Managed Investments Trust; PaineWebber Managed Municipal Trust; PaineWebber Master Series, Inc.; PaineWebber Municipal Series; PaineWebber Mutual Fund Trust; PaineWebber Olympus Fund; PaineWebber Financial Services Growth Fund Inc.; PaineWebber RMA Money Fund, Inc.; PaineWebber RMA Tax-Free Fund, Inc.; PaineWebber Securities Trust; PaineWebber Municipal Money Market Series; PaineWebber Investment Trust; PaineWebber Investment Trust II; PaineWebber Investment Trust III; Liquid Institutional Reserves; PaineWebber Select Fund (together, the ''Funds'') [1]; Mitchell Hutchins Asset Management Inc. (''Mitchell Hutchins''); and PaineWebber Incorporated (''PaineWebber'').

RELEVANT ACT SECTIONS: Order requested under section 6(c) of the Act granting an exemption from section 12(d)(1) of the Act and under sections 6(c) and 17(b) of the Act granting an exemption from section 17(a) of the Act.

SUMMARY OF APPLICATION: The order would permit certain PaineWebber funds to operate as ''funds of funds'' by investing in affiliated open-end investment companies in excess of the percentage limitations of section 12(d)(1).

FILING DATES: The application was filed on August 13, 1996.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on October 25, 1996, and should be accompanied by proof of service on applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants, c/o PaineWebber, 1285 Avenue of the Americas, New York, NY 10019, Attention: Victoria E. Schonfeld, Esq.; and Wilmer, Cutler & Pickering, 2445 M Street, NW., Washington, DC 20037, Attention: Jeremy N. Rubenstein, Esq. & James E. Anderson, Esq.

FOR FURTHER INFORMATION CONTACT: David W. Grim, Staff Attorney, at (202) 942–0571, or Alison E. Baur, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicants' Representations

1. Each Fund is organized either as a Maryland corporation or a Massachusetts business trust and is registered under the Act as an open-end management investment company. PaineWebber Select Fund is a series company that initially will offer one or more series. The series of the PaineWebber Select Fund, together with certain series of other Funds and certain other Funds that do not offer their securities in separate series, are hereinafter referred to as the ''Select Funds.'' Any Fund that is not a Select Fund is hereinafter referred to as an ''Underlying Fund.'' Applicants propose to invest substantially all of the assets of the Select Funds in shares of the Underlying Funds.

2. PaineWebber is a publicly owned securities brokerage, investment banking, and asset management firm offering a broad range of services to corporations, institutions, and substantial private investors worldwide. Mitchell Hutchins is a wholly-owned subsidiary of PaineWebber. PainWebber and Mitchell Hutchins are each registered as a broker-dealer under the Securities Exchange Act of 1934 and as an investment adviser under the Investment Advisers Act of 1940. PaineWebber or Mitchell Hutchins is the investment adviser for each of the Funds. PaineWebber or Mitchell Hutchins is also the principal underwriter for each of the Funds.

3. The Select Funds have been designed to satisfy the demand of investors for a simple and cost-effective means of obtaining professional investment allocation of their assets among a diversified group of mutual funds. Pursuant to its investment objective and its policies, each Select Fund will invest in shares of Underlying Funds, and in no event will hold investment securities other than shares of Underlying Funds and cash equivalents. A Select Fund will not invest in an Underlying Fund unless the Underlying Fund may not acquire securities of any other investment company in excess of the limits contained in section 12(d)(1)(A), except for securities received as a dividend or as a result of a plan of reorganization of any company. Applicants currently expect that the Select Funds will not pay sales loads or bear expenses under rule 12b–1 plans in connection with the Select Funds' investments in Underlying Fund shares. If a Select Fund in the future determines to invest in shares of Underlying Funds that may incur sales charges, it will do so only in conformity with the NASD restrictions on aggregate sales charges.

4. PaineWebber and Mitchell Hutchins are considering charging an advisory fee, presently expected to be up to a maximum of 50 basis points (.50%) (which may be waived initially), for allocating assets for the different Select Funds, monitoring general economic conditions, and providing other advisory services. Although PineWebber and Mitchell Hutchins would also earn advisory fees arising by virtue of their investment advisory contracts with the Underlying Funds, these fees will not be duplicative of any fee charged directly to the Select Funds.

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[1] The term ''Fund'' means, as the context requires, each of the above-referenced investment companies acting on its own behalf, or, if it is a series company, acting on behalf of one or more of its series; the term may also mean, as the context requires, the separate series of each Fund.

Existing Funds that intend to rely on the requested order, including Underlying Funds (as hereinafter defined), have been named as applicants. Other Funds do not presently intend to rely on the requested order, but may do so in the future in accordance with the terms of the application.

Any advisory fee charged at the level of the Select Funds will compensate PaineWebber and Mitchell Hutchins for services that are unique to the Select Funds and are not provided at the Underlying Fund level.

5. Applicants request that any relief granted pursuant to the application also apply to each open-end management investment company or series thereof that is or will be part of a group of investment companies that holds itself out to investors as related companies for purposes of investment and investor services (i) for which PaineWebber or any entity controlling, controlled by, or under common control with PaineWebber now or in the future acts as principal underwriter; or (ii) for which PaineWebber or any entity controlling, controlled by, or under common control with PaineWebber now or in the future acts as investment adviser.

Applicants' Legal Analysis

A. Section 12(d)(1)

1. Section 12(d)(1)(A) provides that no registered investment company may acquire securities of another investment company if such securities represent more than 3% of the acquired company's outstanding voting stock, more than 5% of the acquiring company's total assets, or if such securities, together with the securities of any other acquired investment companies, represent more than 10% of the acquiring company's total assets. Section 12(d)(1)(B) provides that no registered open-end investment company may sell its securities to another investment company if the sale would cause the acquiring company to own more than 3% of the acquired company's voting stock, or if the sale would cause more than 10% of the acquired company's voting stock to be owned by investment companies.

2. Section 6(c) provides that the SEC may exempt persons or transactions if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants request an order under section 6(c) exempting them from section 12(d)(1) to permit the Select Funds to invest in the Underlying Funds in excess of the percentage limitations of section 12(d)(1).

3. Applicants state that section 12(d)(1), as originally adopted and as amended in 1970, is intended to mitigate or eliminate actual or potential abuses that might arise when an investment company acquires shares of another investment company. These abuses include the layering of sales charges and advisory fees and the acquiring fund imposing undue influence over the management of the acquired funds through the threat of large-scale redemptions.

4. Applicants state that the proposed fund of funds structure contains no layering of sales charges or advisory fees. Layering of sales charges will be avoided because applicants currently expect that the Select Funds will not pay sales loads or bear experiences under rule 12b–1 plans in connection with the Select Funds' investments and holdings in Underlying Fund shares. The fact that applicants have reserved the right to have different sales load structures in the future, which may include the payment of sales charges or service fees at both the Select Fund and Underlying Fund level, does not permit any excessive or duplicative sales related charges due to the substantial protections provided by the application. If a Select Fund in the future determines to invest in shares of an Underlying Fund that also bears sales charges or service fees, it will do so only in conformity with the NASD's restrictions on aggregate sales charges and service fees. In addition, a Select Fund will pay no sales charge on its investments in Underlying Funds unless such charges have been reviewed and approved by the Select Fund's directors or trustees who are not ''interested persons,'' as defined in section 2(a)(19) of the Act (''Independent Trustees'').

5. As stated above, PaineWebber and Mitchell Hutchins are considering charging an advisory fee, presently expected to be up to a maximum of 50 basis points (.50%) (which may be waived initially). Applicants state that the advisory fees charged to the Select Funds and the Underlying Funds in which they invest will not be duplicative. If PaineWebber and Mitchell Hutchins determine to charge an advisory fee for the allocation services, or to increase any advisory fee borne by a Select Fund, the fees will conform to the Independent Trustee approval requirements of condition 4 below. The approval process is designed to ensure that any advisory fee that may be borne by any Select Fund will be for services that augment, rather than duplicate, the services provided to the Underlying Funds.

6. Applicants state that there is no basis for the concern that the Select Funds would exercise influence over the management of the Underlying Funds by the threat of redemptions. Applicants contend that excessive control from the threat of redemption and the accompanying loss of advisory fees is not present in the context of a fund of funds involving only funds from the same group of investment companies. Because the Select Funds will acquire only shares of Underlying Funds, a redemption from one Underlying Fund will simply lead to the placing of the proceeds into another Underlying Fund.

7. Condition 2 below prohibits a Select Fund from investing in any Underlying Fund unless the Underlying Fund may not acquire securities of any other investment company in excess of the limits contained in section 12(d)(1)(A) of the Act, except for securities received as a dividend or as a result of a plan of reorganization of any company. The exception for securities received as a dividend or as a result of a plan of reorganization is based on section 12(d)(1)(D) of the Act, which permits an investment company to exceed the limits contained in section 12(d)(1)(A) if it acquires investment company shares as a dividend, as a result of an offer of exchange, or pursuant to a plan of reorganization (other than a plan devised for the purpose of evading section 12(d)(1)(A)). Applicants state that no Underlying Fund would participate in any plan of reorganization devised for the purpose of evading the provisions of section 12(d)(1)(A). Applicants assert that the legislative history of section 12(d)(1)(D) indicates that the enumerated exceptions are warranted because they do not involve any new commitment on the part of the acquiring investment company, and consequently do not present the abuses section 12(d)(1)(A) was intended to address.

B. Section 17(a)

1. Section 17(a) makes it unlawful for an affiliated person of a registered investment company, or an affiliated person of such person, acting as principal, to sell securities to, or purchase securities from, the company. Because the Select Funs and the Underlying Funds are each advised by PaineWebber and/or Mitchell Hutchins, the Select Funds and the Underlying Funds could be deemed to be affiliates of one another. Purchases by the Select Funds of the shares of the Underlying Funds and the sale by the Underlying Funds of their shares to the Select Funds thus could be deemed to be principal transactions between affiliated persons prohibited by section 17(a).

2. Section 17(b) provides that the SEC shall exempt a proposed transaction from section 17(a) if evidence establishes that: (a) the terms of the

proposed transaction are reasonable and fair and do not involve overreaching; (b) the proposed transaction is consistent with the policies of the registered investment company involved; and (c) the proposed transaction is consistent with the general provisions of the Act. Applicants request an exemption under sections 6(c) and 17(b) for an exemption from section 17(a).[2]

3. Applicants assert that the proposed transactions meet the standards of sections 6(c) and 17(b). As discussed previously, protections against duplicative or excessive advisory fees and sales loads ensure that the consideration to be paid in the proposed transactions will be reasonable and fair. A Select Fund's investment in an Underlying Fund will be in accordance with the Select Fund's investment restrictions and will be consistent with its policies as recited in its registration statement. Moreover, applicants represent that because the proposal provides greater diversification, lower costs, and increased administrative efficiency without diminishing the protections afforded to investors, it is consistent with the purposes of the Act.

Applicants' Conditions

Applicants agree that the order granting the requested relief shall be subject to the following conditions:

1. The Select Funds and each Underlying Fund will be part of the same ''group of investment companies'' as defined in paragraph (a)(5) of rule 11a–3 under the Act.

2. The Select Funds will not invest in an Underlying Fund unless that Fund may not acquire securities of any other investment company in excess of the limits contained in section 12(d)(1)(A) of the Act, except for securities received as a dividend or as a result of a plan of reorganization of any company.

3. At least a majority of each Select Fund's trustees will be Independent Trustees.

4. Prior to approving any advisory contract under section 15 of the Act or promptly upon the termination of a fee waiver, the trustees of each Select Fund, including a majority of the Independent Trustees, will find that the advisory fees charged under such contract, if any, are based on services provided that will be in addition to, rather than duplicative of, the services provided under the advisory contract of any Underlying Fund in which a Select Fund may invest; provided that no such findings will be necessary if the investment adviser to an Underlying Fund waives all advisory fees that may be imposed for serving as investment adviser to the Underlying Fund, or, if only a portion of those advisory fees are waived, the investment adviser or another party reimburses the Underlying Fund for any advisory fee or portion thereof that is not waived. These findings and their basis will be recorded fully in the minute books of the Select Fund.

5. Any sales charges or service fees, as such terms are defined under rule 2830(b) of the NASD Conduct Rules, as may be charged with respect to securities of a Select Fund, when aggregated with any sales charges and/or service fees borne by the Select Fund with respect to shares of an Underlying Fund, will not exceed the limits set forth in rule 2830(d) of the NASD Conduct Rules.

6. Applicants will provide the following information in electronic format to the Chief Financial Analyst of the SEC's Division of Investment Management as soon as reasonably practicable following each fiscal year-end of each Select Fund, unless the Chief Financial Analyst notifies applicants that the information need no longer be submitted: (a) Monthly average total assets of each Select Fund and each Underlying Fund in which a Select Fund invests; (b) monthly purchases and redemptions (other than by exchange) for each Select Fund and each Underlying Fund in which a Select Fund invests; (c) monthly exchanges into and out of each Select Fund and each Underlying Fund in which a Select Fund invests; (d) month-end allocations of each Select Fund's assets among the Underlying Funds in which it invests; (e) annual expense ratios for each Select Fund and each Underlying Fund in which a Select Fund invests; and (f) a description of any vote taken by the shareholders of any Underlying Fund in which a Select Fund invests, including a statement of the percentage of votes cast for and against the proposal by the Select Fund and by the other shareholders of that Underlying Fund.

7. Substantially all of the assets of each Select Fund will be invested in shares of Underlying Funds. Each Select Fund will not hold any investment securities other than shares of Underlying Funds and cash equivalents.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–25624 Filed 10–4–96; 8:45 am]

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[2] Section 17(b) applies to specific proposed transactions, rather than an ongoing series of future transactions. *See Keystone Custodian Funds*, 21 S.E.C. 295, 298–99 (1945). Section 6(c) frequently is used in conjunction with section 17(b) to grant relief from section 17(a) to permit an ongoing series of future transactions.

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of October 7, 1996.

An open meeting will be held on Wednesday, October 9, 1996, at 10 a.m. A closed meeting will be held on Wednesday, October 9, 1996, following the 10 a.m. open meeting. A closed meeting will be held on Thursday, October 10, 1996, at 10 a.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9)(A) and (10) and 17 CFR 200.402(a) (4), (8), (9)(A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(i) and (10), permit consideration of the scheduled matters at the closed meeting.

Commissioner Johnson, as duty officer, voted to consider the items listed for the closed meeting in a closed session.

The subject matter of the open meeting scheduled for Wednesday, October 9, 1996, at 10 a.m., will be:

(1) The Commissioner will hear oral argument on an appeal by officers and managers of the Stuart-James Co., Inc., formerly a registered broker-dealer. For further information, please contact: George Zornada at (202) 942–0968.

(2) The Commission will consider whether to issue a release adopting rule and form changes designed to streamline registrant filing requirements with respect to financial statements of significant acquisitions. For further information, please contact: Douglas Tanner, Associate Chief Accountant, Office of Chief Accountant, Division of Corporation Finance, at (202) 942–2960.

(3) The Commission will consider whether to issue a release proposing rules designed to facilitate U.S. press access to offshore press activities. The rules would clarify the conditions under which journalists may be provided access to offshore press conferences, offshore press meetings and press related materials released offshore, where a present or proposed offering of

securities or tender offer is discussed, without violating the provisions of Section 5 of the Securities Act, or the procedural requirements of the tender offer rules promulgated under the Williams Act. For Further Information, Please Contact: Luise M. Welby, Special Counsel, Office of International Corporate Finance, Division of Corporation Finance, at (202) 942–2990.

(4) The Commission will consider whether to issue a release adopting rule and form changes designed to require registrants to report sales of equity securities that have not been registered under the Securities Act, including securities sold in reliance on Regulation S. For Further Information, Please Contact: Walter Van Dorn, Special Counsel, Office of International Corporate Finance, Division of Corporation Finance, at (202) 942–2990.

The subject matter of the closed meeting scheduled for Wednesday, October 9, 1996, following the 10 a.m. open meeting, will be: Post argument discussion.

The subject matter of the closed meeting scheduled for Thursday, October 10, 1996, at 10 a.m., will be:

Institution and settlement of injunctive actions.

Institution and settlement of administrative proceedings of an enforcement nature.

Formal order of investigation.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 942–7070.

Dated: October 3, 1996.

Jonathan G. Katz,

Secretary.

[FR Doc. 96–25826 Filed 10–3–96; 3:53 pm]

BILLING CODE 8010–01–M

[Release No. 34–37744; File No. SR–Amex–96–27]

Self-Regulatory Organizations; Order Granting Approval of a Proposed Rule Change and Notice of Filing and Order Granting Accelerated Approval of Amendment Nos. 1 and 2 to the Proposed Rule Change by the American Stock Exchange, Inc. Relating to Healthcare/Biotechnology Market Index Target-Term Securities (''MITTS'')

September 27, 1996.

I. Introduction

On July 15, 1996, the American Stock Exchange, Inc. (''Amex'' or ''Exchange''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') a proposed rule change to list and trade Market Index Target-Term Securities (''MITTS''),[3] the return on which is based upon an equal-dollar weighted portfolio of 26 healthcare/biotechnology industry securities (''H/B Index'' or ''Index'').[4] Notice of the proposal appeared in the Federal Register on July 24, 1996.[5] No comment letters were received on the proposed rule change. On September 6, 1996, the Amex filed Amendment No. 1 to the proposed rule change.[6] On September 17, 1996, the Amex filed Amendment No. 2 to the proposal.[7] This order approves the proposed rule change, as amended.

II. Description of the Proposal

Under Section 107A of the Amex *Company Guide*, the Exchange may approve for listing and trading securities which cannot be readily categorized under the listing criteria for common and preferred stocks, bonds, debentures, or warrants.[8] The Amex proposes to list for trading under Section 107A of the *Company Guide*, MITTS based on the H/B Index (''H/B MITTS'').[9] The H/B Index will be determined, calculated and maintained solely by the Amex.[10]

The MITTS will conform to the initial listing guidelines under Section 107A [11] and continued listing guidelines under Sections 1001–1003 [12] of the *Company*

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] ''MITTS'' and ''Market Index Target-Term Securities'' are service marks of Merrill Lynch & Co., Inc. (''Merrill Lynch'').

[4] Initially, the H/B Index was comprised of 29 stocks. In Amendment No. 1 the Exchange deleted three stocks from the Index. *See* Amendment No. 1, *infra* note 6. As of July 31, 1996 the Index was comprised of the stocks of the following 26 issuers: Amgen, Inc., Apria Healthcare Group, Inc., Baxter International, Inc., Beverly Enterprises, Biogen, Inc., Chiron Corporation, Columbia/HCA Healthcare Corporation, Emcare Holdings, Inc., Genzyme Corporation, Genesis Health Ventures, Inc., Health Management Associates, Inc., Healthsource, Inc., Healthsouth Corporation, Humana, Inc., Johnson & Johnson, Medpartner/Mullikin, Inc., Neuromedical Systems, Inc., Olsten Corporation, Ornda Healthcorp., Oxford Health Plans, Inc., Phycor, Inc., Quorum Health Group, Inc., Renal Treatment Centers, Inc., Tenet Healthcare Corporation, Total Renal Care Holdings, Inc., and United Healthcare Corporation. According to the Exchange as of September 13, 1996, the market capitalizations of these companies ranged from $207 million to $65.6 billion, and average monthly trading volumes over the preceding six month period ranged from 1.44 million to 52.21 million shares.

[5] *See* Securities Exchange Act Release No. 37447 (July 17, 1996), 61 FR 38485 (July 24, 1996).

[6] In Amendment No. 1 the Exchange revises the list of component securities in the H/B Index by deleting the stocks of Abbott Laboratories, Inc., Caremark International, Inc., and Horizon/CMS Healthcare Corporation. Amendment No. 1 also alters the original proposal to provide that adjustments to the share multiplier will not be made for rights offerings, distributions, recapitalizations, expropriation or nationalization of a foreign issuer or the imposition of certain foreign taxes on shareholders of a foreign issuer. Additionally, Amendment No. 1 provides that H/B MITTS will be traded under the Exchange's equity rules, subject to equity margin requirements, and subject to Amex Rule 411, as described more fully herein. Amendment No. 1 also provides that the H/B Mitts are subject to continued listing provisions set forth in Sections 1001 through 1003 in the Exchange's *Company Guide.* The Exchange intends to submit a proposed rule change in the near future to provide continued listing standards that apply specifically to hybrid securities such as the H/B Mitts. *See* Letter from Claire P. McGrath, Managing Director and Special Counsel, Derivative Securities, Amex, to Livette Lopez, Assistant Director, Office of Market Supervision (''OSM''), Division of Market Regulation (''Division''), Commission, dated September 4, 1996 (''Amendment No. 1'').

[7] In Amendment No. 2, the Amex changes the proposal to provide that the share multiplier of each component also will remain constant in the event of a merger, consolidation, dissolution or liquidation of an issuer. *See* Letter from Claire P. McGrath, Managing Director and Special Counsel, Derivative Securities, Amex, to Ivette Lopez, Assistant Director, OMS, Division, Commission, dated September 13, 1996 (''Amendment No. 2'').

[8] *See* Securities Exchange Act Release No. 27753 (March 1, 1990) (''Hybrid Approval Order'').

[9] The Commission has approved the listing and trading on the New York Stock Exchange of MITTS based upon portfolios of securities representing (1) telecommunications companies, (2) European companies, (3) health care companies, (4) U.S. real estate investment trusts, and (5) restructuring companies. *See* Securities Exchange Act Release Nos. 32840 (September 2, 1993), 58 FR 47485 (September 9, 1993); 33368 (December 22, 1993), 58 FR 68975 (December 29, 1993); 34655 (September 12, 1994), 59 FR 47966 (September 19, 1994); 34691 (September 20, 1994), 59 FR 49264 (September 27, 1994); and 34692 (September 20, 1994), 59 FR 49267 (September 27, 1994) (''MITTS Approval Orders''). The Commission has also approved the listing and trading on the Amex of hybrid securities similar to MITTS, based upon portfolios of securities representing various industries, including, among others, (1) telecommunications companies, (2) banking industry stocks, (3) real estate investment trusts, and, most recently, (4) the ten highest yielding stocks in the Dow Jones Industrial Average. *See* Securities Exchange Act Release Nos. 33495 (January 19, 1994), 59 FR 3883 (January 27, 1994); 34848 (October 17, 1994), 59 53217 (October 21, 1994); 36130 (August 22, 1995), 60 FR 44917 (August 29, 1995); and 37533 (August 7, 1996) 61 FR 42075 (August 13, 1996).

[10] The Ending Portfolio Value, however, will be determined by Merrill, Lynch, Pierce, Fenner & Smith, Incorporated (''Calculation Agent''). *See infra* note 14.

[11] The initial listing standards for MITTS require: (1) a minimum public distribution of one million units; (2) a minimum of 400 shareholders; (3) a market value of at least $4 million; and (4) a term of at least one year. In addition, the listing guidelines provide that the issuer have assets in excess in excess of $100 million, stockholders's equity of at least $10 million, and pre-tax income of at least $750,000 in the last fiscal year or in two of the three prior fiscal years. In the case of an issuer which is unable to satisfy the earnings criteria stated in Section 101 of the *Company Guide*, the Exchange will require the issuer to have the following: (1) assets in excess of $200 million and stockholders' equity of at least $10 million; or (2) assets in excess of $100 million and stockholders' equity of at least $20 million.

[12] The Exchange's continued listing guidelines are set forth in Sections 1001 through 1003 of Part

Guide. MITTS are non-callable senior hybrid debt securities of Merrill Lynch that provide for a single payment at maturity, and will bear no periodic payments of interest. H/B MITTS will entitle the owner at maturity to receive the principal amount, plus an amount based upon the percentage change between the ''Benchmark Portfolio Value'' and the ''Ending Portfolio Value. '' [13] Because the cash amount investors will receive at settlement is based on the difference between the Ending Portfolio Value and the Benchmark Portfolio Value, beneficial owners of H/B Mitts will receive a cash amount only to the extent the Ending Portfolio Value exceeds the Starting Portfolio Value by 12% to 18%. The ''Ending Portfolio Value'' is the value of the H/B Index upon the expiration of the H/B MITTS approximately five years from the pricing date.[14] The Ending Portfolio Value will be used in calculating the amount owners will receive upon maturity.

H/B MITTS are cash-settled in U.S. dollars [15] and do not give the holder any right to receive a portfolio security or any other ownership right or interest in the portfolio securities, although the return on the investment is based on the aggregate portfolio value of the H/B Index securities.

Components of the H/B Index approved pursuant to this filing will meet the following criteria: (1) A minimum market value of at least 75% million, except that up to 10% of the component securities in the Index may have a market value of $50 million; (2) average monthly trading volume in the last six months of not less than 1,000,000 shares, except that up to 10% of the component securities in the Index may have an average monthly trading volume of 500,000 shares or more in the last six months; (3) 90% of the Index's numerical value and at least 80% of the total number of component securities will meet the then current criteria for standardized option trading set forth in Exchange Rule 915; and (4) all component stocks will either be listed on the Amex, the New York Stock Exchange, or traded through the facilities of the National Association of Securities Dealers Automated Quotation System and reported National Market System securities.

As of September 13, 1996, the market capitalizations of the initial portfolio of securities representing the Index ranged from a high of $65.6 billion to a low of $207 million. The average monthly trading volume for the last six months, as of the same date, ranged from a high of 52.21 million shares to a low of 1.44 million shares.

At the outset, each of the securities in the H/B Index will represent approximately an equal percentage of the Starting Portfolio Value of the Index. Specifically, each security included in the portfolio will be assigned a multiplier on the date of issuance so that the security represents approximately an equal percentage of the value of the entire portfolio on the date of issuance (*i.e.* the Index will be ''equal-dollar weighted.'') The multiplier indicates the number of shares (or fraction of one share) of a security, given its market price on an exchange or through NASDAQ, to be included in the calculation of the portfolio. Accordingly, each of the 26 companies included in the Index initially will represent approximately 3.84 percent of the total portfolio at the time of issuance. The Index initially will be set to provide a Starting Portfolio Value of 100.00 at the close of trading on the day preceding its selection. The value of the Index at any time will equal the sum of the products of the current market price for each stock underlying the Index and the applicable share multiplier.

The multiplier of each component stock in the Index will remain fixed unless adjusted for certain corporate events, such as payment of a dividend other than an ordinary cash dividend, a distribution of stock of another issuer to its shareholders, stock split, reverse stock split, or reorganization.[16] In these limited circumstances, the multiplier of the affected security in the Index may be adjusted to maintain the component's relative weight in the Index at the level immediately prior to the corporate action. In all cases, the multiplier will be adjusted, if necessary, to ensure Index continuity.

If the issuer of a stock included in the Index were to no longer exist, whether by reason of a merger, acquisition or similar type of corporate transaction, a value equal to the stock's final value will be assigned to the stock for the purpose of calculating the Index. For example, if a company included in the Index were acquired by another company, a value will be assigned to the company's stock equal to the value per share at the time the acquisition occurred. If the issuer of stock included in the Index is in the process of liquidation or subject to a bankruptcy proceeding, insolvency, or other similar adjudication, such security will continue to be included in the Index so long as a market price for such security is available. If a market price is no longer available for an Index stock due to circumstances including but not limited to, liquidation, bankruptcy, insolvency, or any other similar proceeding, then the security will be assigned a value of zero when calculating the Index for so long as no market price exists for that security.

The Exchange will calculate the Index continuously and, similar to other stock index values published by the Exchange, the value of the Index will be disseminated every 15 seconds over the Consolidated Tape Association's Network B. The Index value will equal the sum of the products of the most recently available market prices and the applicable multipliers for the component securities.

H/B MITTS may not be redeemed prior to maturity and are not callable by the issuer.[17] Holders of H/B MITTS will only be able to cash-out of their investment by selling the security on the Amex. Because H/B MITTS are linked to a portfolio of equity securities, the Amex's existing equity floor trading rules will apply to the trading of H/B MITTS. First, pursuant to Amex Rule 411, the Exchange will impose a duty of due diligence on its members and member firms to learn the essential facts relating to every customer prior to

10 to the Exchange's *Company Guide.* Section 1002(b) of the *Company Guide* states that the Exchange will consider removing from listing any security where, in the opinion of the Exchange, it appears that the extent of public distribution or aggregate market value has become so reduced to make further dealings on the Exchange inadvisable. With respect to continued listing guidelines for distribution of the H/B MITTS, the Exchange will rely, in part, on the guidelines for bonds in Section 1003(b)(iii). Section 1003(b) provides that the Exchange will normally consider suspending dealings in, or removing from the list, a security if the aggregate market value or the principal amount of bonds publicly held is less than $400,000. The Exchange is in the process of developing continued listing standards that apply specifically to hybrid securities such as the MITTS proposed herein. If the Exchange considers delisting the H/B MITTS prior to adopting its own guidelines, the Exchange would consider the NYSE's recently adopted continued listing standards when making its decision. These guidelines contain minimum criteria for public holders, aggregate market value, and publicly held shares. *See* Securities Exchange Act Release No. 37238 (May 22, 1996) (Order approving NYSE continued listing guidelines for hybrid securities). *See also* Amendment No. 1, *supra note 6.*

[13] The Benchmark Portfolio Value will be 12% to 18% (the actual percentage will be determined on the date the MITTS are priced by Merrill Lynch for initial sale to the public) greater than the ''Starting Portfolio Value'' which will be set at 100.

[14] The Ending Portfolio Value, as determined by the Calculation Agent, will equal the average (*i.e.* arithmetic mean) of the closing values of the portfolio on certain days, or if certain events occur, the closing value of the portfolio on a single day prior to the maturity of the securities.

[15] *See* Amendment No. 1, *supra* note 6.

[16] *See* Amendment Nos. 1 and 2, *supra* notes 6 and 7.

[17] *See* Amendment No. 1, *supra* note 6.

trading H/B MITTS.[18] Second, the Amex has adopted a heightened suitability standard that will apply to recommendations in H/B MITTS. In particular, before a member or member organization recommends a transaction in H/B MITTS, such member must make a determination that H/B MITTS are suitable for such customer and the person making the recommendation should have a reasonable basis for believing that the customer has such knowledge and experience in financial matters that he may reasonably be expected to be capable of evaluating the risks and the special characteristics of the recommended transaction, and is financially able to bear the risks of the recommended transaction.[19] Third, H/B MITTS will be subject to the equity margin rules of the Exchange.[20] Finally, in accordance with the Amex's Hybrid Approval Orders, the Exchange will, prior to trading H/B MITTS, distribute a circular to the membership providing guidance with regard to member firm compliance responsibilities, including the heightened suitability standard discussed above, when handling transactions in H/B MITTS and highlighting the special risks and characteristics of H/B MITTS.[21]

III. Commission Findings and Conclusions

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of Section 6(b)(5).[22] Specifically, the Commission believes that providing for exchange-trading of H/B MITTS will offer a new and innovative means of participating in the market for healthcare/biotechnology securities. In particular, the Commission believes that H/B MITTS will permit investors to gain equity exposure in such companies, while at the same time, limiting the downside risk of the original investment. Accordingly, for the same reasons as discussed in the MITTS Approval Orders, the Commission finds that the listing and training of H/B MITTS is consistent with the Act.[23]

As with other MITTS products, H/B MITTS are not leveraged instruments, however, their price will still be derived and based upon the underlying linked security. Accordingly, the level of risk involved in the purchase or sale of H/B MITTS is similar to the risk involved in the purchase or sale of traditional common stock. Nonetheless, because the final rate of return of a MITTS is derivatively priced, based on the performance of a portfolio of securities, and investors will only participate in a limited amount of appreciation,[24] there are several issues regarding the trading of this type of product.

The Commission notes that the Exchange's rules and procedures that address the special concerns attendant to the trading of hybrid securities will be applicable to H/B MITTS. In particular, by imposing the hybrid listing standards, heightened suitability, disclosure, and compliance requirements noted above, the Commission believes the Exchange has addressed adequately the potential problems that could arise from the hybrid nature of H/B MITTS. Moreover, the Exchange will distribute a circular to its membership calling attention to the specific risks associated with H/B MITTS,[25] and the suitability standards which the Amex will apply to transactions in H/B MITTS.[26]

The Commission realizes that H/B MITTS are dependent upon the individual credit of the issuer, Merrill Lynch. To some extent this credit risk is minimized by the Exchange's listing standards in Section 107A of the *Company Guide* which provide that only issuers satisfying substantial asset and equity requirements may issue securities such as MITTS. In addition, the Exchange's hybrid listing standards further require that H/B MITTS have at least $4 million in market value.[27] In any event, financial information regarding Merrill Lynch, in addition to the information on the issuers of the underlying securities comprising the Index, will be publicly available.[28]

The Commission also has a systemic concern, however, that a broker-dealer, such as Merrill Lynch, or a subsidiary providing a hedge for the issuer will incur position exposure. As discussed in the MITTS Approval Orders, the commission believes this concern is minimal given the size of the H/B MITTS issuance in relation to the net worth of Merrill Lynch.[29]

The Commission also believes that the listing and trading of H/B MITTS should not unduly impact the market for the underlying securities comprising the Index. First, the underlying securities comprising the Index are well-capitalized, highly liquid stocks. Second, because all of the components of the Index will be equally weighted, no single stock or group of stocks will likely dominate the Index. Finally, the issuers of the underlying securities comprising the Index, are subject to reporting requirements under the Act, and all of the portfolio securities are either listed or traded on, or traded through the facilities of, U.S. securities markets. Additionally, the Amex's surveillance procedures will serve to deter as well as detect any potential manipulation.

Finally, the Commission notes that the value of the Index will be disseminated at least once every 15 seconds throughout the trading day. The Commission believes that providing access to the value of the Index at least once every 15 seconds throughout the trading day is extremely important and will provide benefits to investors in the product.

The Commission finds good cause for approving amendment Nos. 1 and 2 to the proposed rule change prior to the thirtieth day after the date of publication of notice thereof in the Federal Register. Amendment No. 1 revises the initial portfolio of securities comprising the Index by deleting three of the original proposed securities, includes various specifications regarding the H/B MITTS, and alters the original proposal to provide that adjustments to the share multiplier will not be made for rights offerings, distributions, recapitalizations, expropriation or nationalization of a foreign issuer or the imposition of certain foreign taxes on shareholders of a foreign issuer. Additionally Amendment No. 1 states that H/B MITTS will be traded under the Exchange's equity rules, subject to equity margin requirements, and subject to Amex Rule 411, as described above. Amendment No. 1 also provides that the H/B MITTS are subject to continued listing provisions set forth in Sections 1001 through 1003 in the Exchange's

[18] *See* Amendment No. 1, *supra* note 6. Amex Rule 411 requires that every member, member firm or member corporation use due diligence to learn the essential facts relative to every customer and to every order or account accepted.

[19] Telephone Conversation between Sharon Lawson, Assistant Director, OMS, Division, Commission and Michael T. Bickford, Vice President, Amex, on September 27, 1996.

[20] *See* Amendment No. 1, *supra* note 6.

[21] The Commission expects such circular to, among other things, highlight the payment methodology upon settlement and, in particular, that investors will only participate in appreciation to the extent that the Index value appreciates above a certain amount. *See supra* note 13 and accompanying text.

[22] 15 U.S.C. 78f(b)(5).

[23] *See* MITTS Approval Orders, *supra* note 9.

[24] *See supra* note 13 and accompanying text.

[25] *See supra* note 21.

[26] *See supra* note 19 and accompanying text.

[27] *See* Amex Company Guide § 107A.

[28] The companies that comprise the Index are reporting companies under the Act.

[29] *See* MITTS Approval Orders, *supra* note 9.

Company Guide. The Commission believes that Amendment No. 1 clarifies and strengthens the Exchange's proposal by providing additional information, similar to that provided for other MITTS products previously approved by the Commission, and by stating the specific continued listing guidelines that will apply to H/B MITTS which should help to ensure a minimal level of depth and liquidity for continued trading of the product on the Amex. The Commission believes that Amendment No. 2 also clarifies the Exchange's proposal by providing that no adjustments to the share multiplier for a component stock will be made in the event of merger, consolidation, dissolution or liquidation of an issuer. Accordingly, the Commission believes it is consistent with Section 6(b)(5) of the Act to approve Amendment Nos. 1 and 2 on an accelerated basis.

Interested persons are invited to submit written data, views and arguments concerning Amendment Nos. 1 and 2. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the Amex. All submissions should refer to File No. SR–Amex–96–27 and should be submitted by October 28, 1996.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[30] that the proposed rule change (File No. SR–Amex–96–27), as amended, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[31]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–25623 Filed 10–4–96; 8:45 am]

BILLING CODE 8010–01–M

[30] 15 U.S.C. 78S(b)(2)

[31] 17 CFR 200.30–3(a)(12).

[Release No. 34–37752; File No. SR–MBSCC–96–04]

Self-Regulatory Organizations; MBS Clearing Corporation; Order Approving a Proposed Rule Change to Establish Term Limits for the Chairman of the Board of Directors

September 30, 1996.

On June 24, 1996, MBS Learning Corporation; Order Approving a Proposed Rule Change to Establish Term Limits for the Chairman of the Board of Directors

On June 24, 1996, MBS Clearing Corporation (''MBSCC'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change (File No. SR–MBSCC–96–06) pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') to establish term limits for the chairman of MBSCC's Board of Directors.[1] Notice of the proposal was published in the Federal Register On August 14, 1996.[2] No comment letters were received. For the reasons discussed below, the Commission is approving the proposed rule change.

I. Description

The rule change amends Section 5.3 of MBSCC's by-laws, regarding the term of office, removal, and vacancies of officers, to limit the term of office for the Chairman of the Board to not more than four consecutive one-year terms.

II. Discussion

Section 17A(b)(3)(C)[3] of the Act requires that the rules of a clearing agency be designed to assure a fair representation of its shareholders or members and participants in the selection of its directors and administration of its affairs. The Commission believes that MBSCC's rule change is consistent with MBSCC's obligations under the Act because it should create greater diversity in the individuals who will serve as MBSCC's Chairman of the Board and thereby should promote the fair representation of participants in the administration of MBSCC's affairs.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act and in particular with the requirements of Section 17A of the Act and the rules and regulations thereunder.

[1] U.S.C. § 78s(b)(1) (1988).

[2] Securities Exchange Act Release No. 37541 (August 8, 1996), 61 FR 42298.

[3] 15 U.S.C. § 78q–1(b)(3)(C) (1988).

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR–MBSCC–96–04) be, and hereby is, approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[4]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–25620 Filed 10–4–96; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–37767; File No. SR–PSE–96–29]

Self-Regulatory Organizations; Pacific Stock Exchange, Inc.; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change and Amendment No. 1 Thereto Relating to a One-Year Extension of the Lead Market Maker System Pilot Program

September 30, 1996.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 22, 1996, the Pacific Stock Exchange, Inc. (''PSE'' or ''Exchange'') submitted to the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I and II below, which items have been prepared by the PSE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and to grant accelerated approval of the proposed rule change and an amendment thereto.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Commentary .01 to PSE Rule 6.82, ''Lead Market Maker Pilot Program,'' states that the PSE's Lead Market Maker (''LMM'') system pilot program will expire on September 30, 1996. The PSE proposes to amend Commentary .01 to extend the pilot program, so that it will be set to expire on September 30, 1997.[3]

[4] 17 CFR 200.30–3(a)(12) (1996).

[1] 15 U.S.C. 78s(b)(1) (1988).

[2] 17 CFR 240.19b–4 (1994).

[3] The PSE originally submitted a request for permanent approval of its Lead Market Maker (''LMM'') System Pilot Program. On September 30, 1996, the PSE submitted Amendment No. 1 to the proposed rule change. *See* Letter from Michael Pierson, Senior Attorney, Regulatory Policy, Pacific Stock Exchange, to Janet Russell-Hunter, Special Counsel, Division of Market Regulation, SEC, dated September 30, 1996. In Amendment No. 1, the PSE withdrew the provision requesting permanent approval of the LMM pilot program and requested a one-year extension of the pilot program. The PSE

Continued

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

On January 17, 1990, the Commission approved the Exchange's LMM System on a pilot program basis.[4] Since that time, the Commission has approved extensions to the pilot program.[5] The pilot program is currently set to expire on September 30, 1996.

In connection with its filing with the Commission, the Exchange included a pilot program report for the period August 18, 1995 to July 18, 1996.[6] In its report, the Exchange indicated that it believes, based on the pilot's performance, that the LMM System is viable and effective and that continuation of the pilot program is warranted based on the importance of maintaining the quality, efficiency, and competitiveness of the Exchange's markets in a multiple trading environment.

The Exchange believes that its proposal is consistent with Section 6(b) of the Act in general, and Section 6(b)(5) in particular, in that it is designed to promote just and equitable principles of trade and to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of Section 6(b)(5) of the Act[7] that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, and, in general, to protect investors and the public. The Commission concludes, as it did in approving the LMM pilot program, that the pilot program may enhance the market making mechanism on the PSE, thereby improving the markets for listed options on the Exchange. Specifically, the Commission believes that the LMM pilot may improve the PSE's market making capabilities by creating long-term commitments to options classes. Moreover, the pilot program will continue with adequate due process safeguards in the LMM selection and termination procedures and will retain procedures that prevent the misuse of material non-public LMM information by either an LMM or a broker-dealer affiliated with an LMM. The Commission notes, however, that before the pilot program can be approved on a permanent basis, or further extended, the PSE must provide the Commission with an updated report on the operation of the pilot program.

Specifically, before requesting permanent approval, or further extension, of the pilot program, the PSE must submit an updated pilot program report by June 1997 that addresses: (1) whether there have been any complaints regarding the operation of the pilot; (2) whether the PSE has taken any disciplinary or performance action against any member due to the operation of the pilot; (3) the number of LMMs involved in the pilot; (4) the extent to which the pilot has been used on the PSE; (5) whether the PSE has terminated or replaced an LMM and the reasons thereof; (6) the impact of the pilot on the bid/ask spreads, depth and continuity in PSE options markets; and (7) whether the PSE has taken any actions or there have been any complaints against LMMs or associated broker-dealers relating to improper activity as a result of LMM affiliations with upstairs firms.

The Commission finds good cause for approving the Exchange's proposed rule change, including Amendment No. 1, prior to the thirtieth day after the date of publication of notice of filing thereof in the Federal Register because the PSE has not indicated that there have been any problems associated with the operation of the LMM system pilot program and because the Commission has not received any adverse comments concerning the pilot program. In addition, the Commission believes good cause exists to approve the extension of the LMM pilot program on an accelerated basis to allow the pilot program to continue uninterrupted.

Based on the above, the Commission believes that the proposal is consistent with Section 6(b)(5) of the Act and that good cause exists to approve the PSE's proposal on an accelerated basis.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the PSE. All submissions should refer to File No. SR–PSE–96–29 and should be submitted by October 28, 1996.

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also requested accelerated approval of the proposed rule change.

[4] *See* Securities Exchange Act Release No. 27631 (January 17, 1990), 55 FR 2462.

[5] *See* Securities Exchange Act Release Nos. 31063 (August 21, 1992), 57 FR 39255; 31635 (December 22, 1992), 57 FR 62414; 33854 (April 1, 1994), 59 FR 16873; 34710 (September 23, 1994), 59 FR 50306; and 36293 (September 28, 1995), 60 FR 52243. *See also* File No. SR–PSE–93–16 (requesting permanent approval of the pilot program) and Amendment Nos. 1–3 thereto (requesting pilot program extensions while the request for permanent approval was pending). On April 20, 1994, the Exchange withdrew File No. SR–PSE–93–16 pursuant to the Commission's request. *See* letter from David P. Semak, Vice President, Regulation, PSE, to Sharon M. Lawson, Assistant Director, Division of Market Regulation, Commission, dated April 20, 1994.

[6] The Exchange has previously submitted pilot program reports to the Commission dated September 18, 1992, July 26, 1993, and August 23, 1995. *See* File Nos. SR–PSE–92–36, SR–PSE–93–16, and SR–PSE–95–20.

[7] 15 U.S.C. 78f(b)(5) (1988).

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[8] that the proposed rule change (SR–PSE–96–29), as amended, is approved on an accelerated basis, and accordingly, that the LMM pilot program is extended until September 30, 1997.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–25622 Filed 10–4–96; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster Loan Area #2880; Amendment #2]

Illinois; Declaration of Disaster Loan Area

In accordance with a notice from the Federal Emergency Management Agency, dated September 24, 1996, the above-numbered Declaration is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to September 30, 1996.

All other information remains the same, i.e., the termination date for filing applications for loans for economic injury is April 25, 1997.

(Catalog of Federal Domestic Assistance Programs Nos. 59002 and 59008)

Dated: September 27, 1996.

Bernard Kulik,

Associate Administrator for Disaster Assistance.

[FR Doc. 96–25633 Filed 10–4–96; 8:45 am]

BILLING CODE 8025–01–U

[Declaration of Disaster Loan Area #2900]

Maryland; Declaration of Disaster Loan Area

As a result of the President's major disaster declaration on September 17, 1996, I find that Allegany and Frederick Counties in the State of Maryland constitute a disaster area due to damages caused by severe storms and flooding associated with Tropical Storm Fran which occurred September 6–9, 1996. Applications for loans for physical damages may be filed until the close of business on November 15, 1996, and for loans for economic injury until the close of business on June 17, 1997 at the address listed below: U.S. Small Business Administration, Disaster Area 1 Office, 360 Rainbow Blvd. South, 3rd Fl., Niagara Falls, NY 14303; or other locally announced locations. In addition, applications for economic injury loans from small businesses located in the following contiguous counties may be filed until the specified date at the above location: Carroll, Garrett, Howard, Montgomery, and Washington Counties in Maryland, and Adams and Somerset Counties in Pennsylvania.

Any counties contiguous to the above-named counties and not listed herein have been previously declared under a separate declaration for the same occurrence.

Interest rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	8.000
Homeowners without Credit Available Elsewhere	4.000
Businesses with Credit Available Elsewhere	8.000
Businesses and Non-Profit Organizations without Credit Available Elsewhere	4.000
Others (Including Non-Profit Organizations) with Credit Available Elsewhere	7.125
For Economic Injury:	
Businesses and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 290008. For economic injury the numbers are 919000 for Maryland and 919100 for Pennsylvania.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: September 20, 1996.

Bernard Kulik,

Associate Administrator for Disaster Assistance.

[FR Doc. 96–25631 Filed 10–4–96; 8:45 am]

BILLING CODE 8025–01–U

[Declaration of Disaster Loan Area #2899]

Pennsylvania; Declaration of Disaster Loan Area

As a result of the President's major disaster declaration on September 13, 1996, I find that Huntingdon, Juniata, Mifflin, Montgomery, and Perry Counties in the State of Pennsylvania constitute a disaster area due to damages caused by flooding associated with Tropical Depression Fran which occurred September 6–8, 1996. Applications for loans for physical damages may be filed until the close of business on November 12, 1996, and for loans for economic injury until the close of business on June 13, 1997 at the address listed below: U.S. Small Business Administration, Disaster Area 1 Office, 360 Rainbow Blvd. South, 3rd Fl., Niagara Falls, NY 14303; or other locally announced locations. In addition, applications for economic injury loans from small businesses located in the following contiguous counties may be filed until the specified date at the above location: Bedford, Berks, Blair, Bucks, Centre, Chester, Cumberland, Dauphin, Delaware, Franklin, Fulton, Lehigh, Northumberland, Philadelphia, and Snyder Counties in Pennsylvania, and Burlington, Camden, and Gloucester Counties in New Jersey.

Interest rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	8.000
Homeowners without Credit Available Elsewhere	4.000
Businesses with Credit Available Elsewhere	8.000
Businesses and Non-Profit Organizations without Credit Available Elsewhere	4.000
Others (Including Non-Profit Organizations) with Credit Available Elsewhere	7.125
For Economic Injury:	
Businesses and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 289908. For economic injury the numbers are 918800 for Pennsylvania and 918900 for New Jersey.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: September 20, 1996.

Bernard Kulik,

Associate Administrator for Disaster Assistance.

[FR Doc. 96–25630 Filed 10–4–96; 8:45 am]

BILLING CODE 8025–01–U

[Declaration of Disaster Loan Area #2903]

Pennsylvania (And Contiguous Counties in New York and Ohio); Declaration of Disaster Loan Area

Erie County and the contiguous counties of Crawford and Warren in the Commonwealth of Pennsylvania, Chautauqua County, New York, and Ashtabula County, Ohio constitute a disaster area as a result of damages caused by flooding which occurred on September 13, 1996. Applications for loans for physical damage may be filed

[8] 15 U.S.C. 78s(b)(2) (1988).

[9] 17 CFR 200.30–3(a)(12) (1994).

until the close of business on November 25, 1996 and for economic injury until the close of business on June 26, 1997 at the address listed below: U.S. Small Business Administration, Disaster Area 1 Office, 360 Rainbow Boulevard South, 3rd Floor, Niagara Falls, New York 14303, or other locally announced locations.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	8.000
Homeowners without Credit Available Elsewhere	4.000
Businesses with Credit Available Elsewhere	8.000
Businesses and Non-Profit Organizations without Credit Available Elsewhere	4.000
Others (Including Non-Profit Organizations) with Credit Available Elsewhere	7.125
For Economic Injury:	
Businesses and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000

The numbers assigned to this disaster for physical damage are 290306 for Pennsylvania, 290406 for New York, and 290506 for Ohio. For economic injury the numbers are 919400 for Pennsylvania, 919500 for New York, and 919600 for Ohio.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: September 26, 1996.

John T. Spotila,

Acting Administrator.

[FR Doc. 96–25632 Filed 10–4–96; 8:45 am]

BILLING CODE 8025–01–U

[Declaration of Disaster Loan Area #2896; Amendment #1]

Puerto Rico; Declaration of Disaster Loan Area

In accordance with notices from the Federal Emergency Management Agency, dated September 14, 16, and 18, 1996, the above-numbered Declaration is hereby amended to include the Municipalities of Adjuntas, Aguada, Aguadilla, Aibonito, Anasco, Arecibo, Augas Buenas, Barceloneta, Barranquitas, Cabo Rojo, Caguas, Camuy, Ciales, Cidrda, Comerio, Corozal, Dorado, Florida, Guayanilla, Humacao, Isabela, Jayuya, Juncos, Laaares, Las Marias, Maricao, Mayaguez, Moca, Morovis, Naguabo, Naranjito, Orocovis, Patillas, Penuelas, Rincon, San Sebastian, San German, Toa Alta, Utuado, Vega Alta, Vega Baja, and Yauco in the Commonwealth of Puerto Rico as a disaster area due to damages caused by Hurricane Hortense beginning on September 9, 1996 and continuing.

In addition, applications for economic injury loans from small businesses located in the following contiguous municipalities in the Commonwealth of Puerto Rico may be filed until the specified date at the previously designated location: Guanica, Hatillo, Hormigueros, Lajas, Manati, Quebradillas, Sabana Grande, and Villalba.

All other information remains the same, i.e., the termination date for filing applications for physical damage is November 11, 1996, and for loans for economic injury the deadline is June 11, 1997.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Date: September 26, 1996.

Bernard Kulik,

Associate Administrator for Disaster Assistance.

[FR Doc. 96–25628 Filed 10–4–96; 8:45 am]

BILLING CODE 8025–01–U

[Declaration of Disaster Loan Area #2895; Amendment #1]

Virginia; Declaration of Disaster Loan Area

In accordance with notices from the Federal Emergency Management Agency, dated September 13, 16, and 24, 1996, the above-numbered Declaration is hereby amended to include the Independent Cities of Bedford, Buena Vista, Emporia, Lexington, and Lynchburg, and the Counties of Alleghany (including the Independent Cities of Clifton Forge and Covington), Amherst, Appomattox, Brunswick, Campbell, Charlotte, Culpeper, Fauquier, Franklin, Frederick (including the Independent City of Winchester), Greene, Greensville, Henry, Highland, Louisa, Lunenberg, Montgomery (including the Independent City of Radford), Orange, Prince Edward, Roanoke (including the Independent Cities of Roanoke and Salem), and Stafford in the Commonwealth of Virginia as a disaster area due to damages caused by Hurricane Fran and associated severe storm conditions, including high winds, tornadoes, wind driven rain, and river and flash flooding beginning on September 5, 1996 and continuing

In addition, applications for economic injury loans from small businesses located in the following contiguous counties may be filed until the specified date at the previously designated location: Amelia, Caroline, Craig, Cumberland, Dinwiddie, Floyd, Fluvanna, Giles, Goochland, Hanover, King George, Nottoway, Patrick, Prince William, Pulaski, Southampton, Spotsylvania (including the Independent City of Fredericksburg), and Sussex in the Commonwealth of Virginia, and Greenbrier and Monroe Counties in West Virginia.

Any counties contiguous to the above-named counties and not listed herein have been previously declared under a separate declaration for the same occurrence.

All other information remains the same, i.e., the termination date for filing applications for physical damage is November 6, 1996, and for loans for economic injury the deadline is June 9, 1997.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: September 26, 1996

Bernard Kulik,

Associate Administrator for Disaster Assistance.

[FR Doc. 96–25629 Filed 10–4–96; 8:45 am]

BILLING CODE 8025–01–U

DEPARTMENT OF STATE

[Public Notice No. 2446]

Shipping Coordinating Committee Subcommittee on Ship Design and Equipment and Associated Bodies; Notice of Meeting

The Shipping Coordinating Committee will conduct an open meeting at 9:30 a.m. on Thursday, October 17, 1996, in Room 2415, at U.S. Coast Guard Headquarters, 2100 2nd Street, SW., Washington, DC 20593. The purpose of the meeting is to prepare for the fortieth session of the Subcommittee on Ship Design and Equipment of the International Maritime Organization (IMO) which is scheduled for February 10–14, 1997, at IMO Headquarters in London, England.

Among other things, items of particular interest are: role of the human element in maritime casualties—guidelines for engine room layout; voyage data recorders; revision of the High Speed Craft Code; ro-ro ferry & bulk carrier safety matters; matters relating to lifesaving; safety of passenger submersible craft; safe ocean towing guidelines; and ship structures matters.

IMO works to develop international agreements, guidelines, and standards for the marine industry. In most cases, these form the basis for class society rules and national standards/regulations. The U.S. Safety of Life at Sea (SOLAS) Working Group supports

the U.S. Representative to the IMO Subcommittee in developing the U.S. position on those issues raised at the IMO Subcommittee meetings. The U.S. SOLAS Working Group serves as an excellent forum for the U.S. maritime industry to express their ideas and participate in the international rulemaking process. All members of the maritime industry are encouraged to send representatives to participate in the development of U.S. positions on those issues affecting your maritime industry and remain abreast of all activities ongoing within the IMO.

Members of the public may attend this meeting up to the seating capacity of the room. Interested persons may seek information by writing: CDR Jim Stamm, U.S. Coast Guard Headquarters, Commandant (G–MSE), 2100 2nd Street, SW., Washington, DC 20593–0001 or by calling: (202) 267–2206.

Dated: September 17, 1996.

Stephen M. Miller,

Secretary, Shipping Coordinating Committee.

[FR Doc. 96–25268 Filed 10–4–96; 8:45 am]

BILLING CODE 4710–07–M

[Public Notice No. 2453]

Shipping Coordinating Committee; Subcommittee on Ocean Dumping; Notice of Meeting

The subcommittee on Ocean Dumping of the Shipping Coordinating Committee will hold an open meeting on Tuesday, October 22, 1996, from 1:00 p.m. to 3:00 p.m. to obtain public comment on the issues to be addressed October 28–November 8, 1996, at the Special Meeting of the Contracting Parties to the London Convention of 1972, which regulates ocean dumping. The results of Nineteenth Meeting of the Scientific Group, held in May 1996, will also be an item for discussion.

The public meeting will be held at the Environmental Protection Agency, Waterside Mall, 401 M Street, S.W., Washington, D.C., 20460, in the Eighth Floor Conference Room of the West Tower. Interested members of the public are invited to attend, up to the capacity of the room. Upon entering the West Tower, those without government identification should dial 260–8199 to obtain clearance.

For further information, please contact Mr. Bryan Wood-Thomas, Office of International Activities, telephone (202) 260–6983.

Dated: October 2, 1996.

Stephen M. Miller,

Executive Secretary, Shipping Coordinating Committee.

[FR Doc. 96–25654 Filed 10–4–96; 8:45 am]

BILLING CODE 4710–09–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Reports, Forms and Recordkeeping Requirements; Agency Information Collection Activity Under OMB Review

AGENCY: Office of the Secretary, Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), this notice announces that the Information Collection Requests (ICRs) abstracted below has been forwarded to the Office of Management and Budget (OMB) for extension of currently approved collections. The ICRs describes the nature of the information collections and their expected burdens. The Federal Register Notice with a 60-day comment period soliciting comments on the following collections of information was published on July 15, 1996 (FR 61, page 36954–36955).

DATES: Comments must be submitted on or before November 6, 1996.

FOR FURTHER INFORMATION CONTACT: Sylvia Barney, (202) 366–6680, and refer to the OMB Control Number.

SUPPLEMENTARY INFORMATION:

Federal Transit Administration (FTA)

1. *Title:* Title VI As It Applies to FTA Grant Programs.

Type of Request: Extension to a currently approved information collection.

OMB Control Number: 2132–0540.

Affected Public: FTA grant recipients.

Abstract: Section 601 of Title VI of the Civil Rights Act of 1964 states: ''No person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.'' This information collection is required by the Department of Justice (DOJ) Title VI Regulation, 28 CFR Part 42, Subpart F (Section 42.406), and DOT Order 1000.12. FTA policies and requirements are designed to clarify and strengthen these regulations. This requirement is applicable to all applicants, recipients, and sub recipients receiving Federal financial assistance. Experience has demonstrated that a program requirement at the application stage is necessary to assure that benefits and services are equitably distributed by grant recipients. The requirements prescribed by the Office of Civil Rights accomplish that objective while diminishing possible vestiges of discrimination among FTA grant recipients. FTA's assessment of this requirement indicated that the formulation and implementation of the Title VI program should occur with a decrease in costs to such applicants and recipients.

All FTA grant applicants, recipients, and sub recipients are required to submit applicable Title VI information to the FTA Office of Civil Rights for review and approval. If FTA did not conduct pre-award reviews, solutions would not be generated in advance and program improvements could not be integrated into projects. FTA's experience with pre-award reviews for all projects and grants suggests this method contributes to maximum efficiency and cost effectiveness of FTA dollars and has kept post-award complaints to a minimum. Moreover, the objective of the Title VI statute can be more easily attained and beneficiaries of FTA funded programs have a greater likelihood of receiving transit services and related benefits on a nondiscriminatory basis.

Estimated Annual Burden: The estimated annual burden is 2,883 hours.

2. *Title:* Nondiscrimination As It Applies to FTA Grant Programs.

Type of Request: Extension to a currently approved information collection.

OMB Control Number: 2132–0542.

Affected Public: FTA grant recipients.

Abstract: All entities receiving Federal financial assistance from FTA are prohibited from discriminating against any employee or applicant for employment because of race, color, creed, sex, national origin, age, or disability. To ensure that FTA's equal employment opportunity (EEO)procedures are followed, FTA requires grant recipients to submit written EEO plans to FTA for approval. FTA's assessment of this requirement shows that the formulating, submitting, and implementing of EEO programs should minimally increase costs for FTA applicants and recipients.

To determine a grantee's compliance with applicable laws and requirements, grantee submissions are evaluated and analyzed based on the following criteria. First, an EEO program must include an EEO policy statement issued by the chief executive officer covering all

employment practices, including recruitment, selection, promotions, terminations, transfers, layoffs, compensation, training, benefits, and other terms and conditions of employment. Second, the policy must be placed conspicuously so that employees, applicants, and the general public are aware of the agency's EEO commitment.

The data derived from written EEO and affirmative action plans will be used by the Office of Civil Rights in monitoring grantees' compliance with applicable EEO laws and regulations. This monitoring and enforcement activity will ensure that minorities and women have equitable access to employment opportunities and that recipients of Federal funds do not discriminate against any employee or applicant because of race, color, creed, sex, national origin, or age, or disability.

Estimated Total Annual Burden: The total estimated annual burden is 6,000 hours.

3. *Title:* Reporting of Technical Activities by FTA Grant Recipients.

Type of Request: Extension to a currently approved information collection.

OMB Control Number: 2132–0549

Affected Public: FTA grant recipients.

Abstract: 49 U.S.C. Sections 5303 and 5313 (a) and (b) authorize the use of Federal funds to assist metropolitan planning organizations (MPOs), states, and local public bodies in developing transportation plans and programs to serve future transportation needs of urbanized areas over 50,000 in population and States throughout the nation. As part of this effort, MPOs are required to consider a wide range of goals and objectives and to analyze alternative transportation system management and investment strategies. These objectives are measured by definable activities such as suburban mobility planning and other related activities.

The information collected by these forms is used to report annually to Congress, the Secretary, and to the FTA Administrator on how grantees are responding to national emphasis areas and congressional direction, and allows FTA to track grantees' use of Federal planning and research funds.

Estimated Total Annual Burden: The total estimated burden is 150 hours.

4. *Title:* Bus Testing Program.

Type of Request: Extension to a currently approved information collection.

OMB Control Number: 2132–0550

Affected Public: FTA grant recipients.

Abstract: 49 U.S.C. Section 5323© provides that no Federal funds appropriated or made available after September 30, 1989, may be obligated or expended for the acquisition of a new bus model (including any model using alternative fuels) unless the bus has been tested at the Bus Testing Center (Center) in Altoona, Pennsylvania. 49 U.S.C. Section 5318(a) further specifies that each new bus model is to be tested for maintainability, reliability, safety, performance (including braking performance), structural integrity, fuel economy, emissions, and noise.

The operator of the Bus Testing Center, the Pennsylvania Transportation Institute (PTI), is under contract to the FTA. PTI operates and maintains the Center, and establishes and collects fees for the testing of the vehicles at the facility. Upon completion of the testing of the vehicle at the Center, a test report is provided to the manufacturer of the new bus model. The bus manufacturer certifies to an FTA grantee that the bus the grantee is purchasing has been tested at the Center. Also, grantees about to purchase a bus use this report to assist them in making their purchasing decisions. PTI maintains a reference file for all the test reports which are made available to the public.

Estimated Total Annual Burden: The total estimated annual burden is 50 hours.

5. *Title:* Prevention of Alcohol Misuse in Transit Operations.

Type of Request: Extension to a currently approved information collection.

OMB Control Number: 2132–0557.

Abstract: The Omnibus Transportation Employee Testing Act of 1991 (Pub.L. 102–143, October 28, 1991, now codified in relevant part at 49 U.S.C. Section 5331) requires any recipient of Federal financial assistance under 49 U.S.C. Sections 5309, 5307, or 5311 or under 23 U.S.C. Section 103(e)(4) to establish a program designed to help prevent accidents and injuries resulting from the misuse of drugs and alcohol by employees who perform safety-sensitive functions. FTA's regulation, 49 CFR Part 654, ''Prevention of Alcohol Misuse in Transit Operations,'' effective March 17, 1994, requires recipients to submit to FTA annual reports containing data which summarize information concerning the recipients' alcohol testing program, such as the number and type of test given, number of positive test results, and the kind of safety-sensitive function the employee performs. FTA uses these data to ensure compliance with the rule, to assess the misuse of alcohol in the transit industry, and to set the random testing rate. The data will also be used to assess the effectiveness of the rule in reducing the misuse of alcohol among safety-sensitive transit employees and making transit safer for the public.

Estimated Total Annual Burden: The total estimated annual burden is 32,480 hours.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street, NW, Washington, DC 20503, Attention OST Desk Officer.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and 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.

Issued in Washington, DC, on October 1, 1996.

Phillip A. Leach,

Clearance Officer, United States Department of Transportation.

[FR Doc. 96–25610 Filed 10–4–96; 8:45 am]

BILLING CODE 4910–62–P

Coast Guard

[CGD 96–044]

Documentation and Marine Safety for an International, Private-Sector, Tug of Opportunity System

AGENCY: Coast Guard, DOT.

ACTION: Notice of meeting; supplemental information.

SUMMARY: This notice provides a summary of the sections of the Interim Report that will be discussed at the meeting on an international, private-sector tug of opportunity system (ITOS) to be held on October 17, 1996. Notice of this meeting was published in the Federal Register on September 12, 1996. This second notice provides additional information to improve the quality of input from the public at the meeting.

DATES: The meeting will be held October 17, 1996, from 9 a.m. to 5 p.m. Written statements and requests to make oral presentations should reach the Coast Guard on or before October 10, 1996. Other comments should reach the Coast Guard on or before October 30, 1996.

ADDRESSES: The meeting will be held on the fourth floor, North Auditorium, Jackson Federal Building, 915 Second Avenue, Seattle, Washington. Written materials may be mailed to the Executive Secretary, Marine Safety Council (G–LRA), U.S. Coast Guard, 2100 Second Street SW., Washington, DC 20593–0001, or may be delivered to room 3406 at the same address between 9:30 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant W.M. Pittman, Office of Response (G–MOR–1), telephone (202) 267–0426, fax (202) 267–4085. The telephone number is equipped to record messages on a 24-hour basis.

SUPPLEMENTARY INFORMATION:

Background Information

On November 28, 1995, the President signed the Alaska Power Administration Asset Sale and Termination Act (Pub. L. 104–58), authorizing exports of Alaskan North Slope (ANS) crude oil when transported in U.S. flag tankers. Section 401 of the statute directs the Coast Guard to submit, within 15 months of enactment of the Act, a plan to Congress on the most cost-effective means of implementing an international private sector tug of opportunity system. The plan is to include a coordinated system of communication, using exiting towing vessels to provide timely emergency response to a vessel in distress transiting the waters within the boundaries of the Olympic Coast Marine Sanctuary or the Strait of Juan de Fuca.

In order to implement this action, the Department of Transportation has required that the Coast Guard establish marine safety requirements concerning crew qualification, tug performance capabilities, and response times which any proposed international tug-of-opportunity system (ITOS) must meet to ensure marine environmental safety. In addition, the Coast Guard has proposed to establish specific ITOS documentation requirements needed to properly describe the operation of any proposed ITOS so that it may be fully evaluated as required by Public Law 104–58.

These marine safety requirements and documentation requirements are contained in the Interim Report on the International, Private-Sector Tug-of-Opportunity System for the Waters of the Olympic National Marine Sanctuary and the Strait of Juan de FICA. Initial copies of this report were provided to interested parties. Additional copies of this report may be obtained by contacting the Office of Response (G–MOR–1), Directorate of Field Operations, U.S. Coast Guard, 2100 Second Street SW., Washington DC 20593–0001 or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT.** This notice provides a summary of the marine safety requirements and documentation requirements contained in the interim report.

A meeting to be held on October 17, 1996, was announced in the Federal Register on September 12, 1996 (61 FR 48202). This meeting is to provide the public with an opportunity to comment on the marine safety and documentation requirements contained in the interim report. The present notice provides a summary of those requirements to assist the public in preparing comments for the October 17, 1996, meeting.

A discussion of both the documentation requirements and the marine safety requirements follows. Any international, private-sector plan submitted for review must respond to the following areas:

Documentation Requirements

1. The Organizational and Operations Structure

(a) Identify the specific purpose of the international, private-sector, tug of opportunity system, which should be to check disabled vessels and tow them, if necessary, using a tug of opportunity. A tug of opportunity is a vessel with towing capabilities designed to save a disabled vessel and to prevent a drift grounding.

(b) Explain methods for tracking commercial vessel movement in relation to the tug of opportunity services provided.

(c) Provide the status of available tugs and their performance capabilities.

(d) Provide expectations for contracted tug response capabilities.

(e) Provide a means for prioritizing competing tug needs for dispatch of tug resources.

(f) Provide for cascading resource situations including identification of additional tug resources and replacement tugs to release other tugs for response.

(g) Provide an explanation of the administrative, financial, technical, and legal processes necessary to ensure an effective tug of opportunity system.

(h) Explain expected basic organization structures, governance, and administration.

(i) Explain needed interactions with other organizations.

(j) Define the mission, member responsibilities, financial commitments, terms of office, rules for operation and compensation, and other related matters.

(k) Explain the expected registration and status of the tug of opportunity system as a legal entity.

(l) Identify the day-to-day functions of the organization.

(m) Identify the functions expected to be performed by contractors or other organizations.

(n) Identify the organizational decision-making process by which a vessel may request assistance or another authority may direct assistance.

(o) Identify the method for matching tug capabilities with vessel requirements per the marine safety requirements.

(p) Identify the minimum performance requirements expected of the tug fleet to meet the range of expected assistance requests, and address special tug performance limiting factors such as specified sea, weather, wind, and current conditions.

(q) Identify the method by which 24-hour, 7-day per week monitoring of tug of opportunity system operations will be achieved.

2. Technology Issues

(a) Identify the hardware and software systems that will be used to identify and communicate with tugs, vessels, and organizations.

(b) Identify vessel transit population characteristics.

(c) Identify those vessel distress conditions that will most likely be encountered in order to assess possible instances of future need.

(d) Identify tug resources and update methods.

(e) Identify the system(s) and equipment that will be used to track a tug's location, onboard equipment, and performance capabilities.

(f) Identify a method for maintaining ready access to the performance characteristics of any tug available for response.

(g) Identify the towing equipment needed on a vessel and on a tug by using the International Maritime Organization towing package requirements or equivalent standards.

(h) Identify any pre-staged equipment packages and plans available for deployment.

(i) Indicate the international, tug of opportunity system response structure that will observe response times.

(j) Identify unique geographical characteristics and seasonal changes pertinent to the area, as well as tug resources that are typically available.

(k) Identify the method(s) by which response time requirements will be communicated, observed, and documented for assistance calls.

(l) Identify the crew qualifications necessary to operate tugs of opportunity

to satisfy the marine safety requirements.

(m) Identify training that is consistent with qualification requirements and the method for its provision.

(n) Indicate the requirements and procedures for conducting periodic testing for certification of capability.

3. Legal Requirements

(a) Identify applicable laws and regulations.

(b) Include any international law, treaty, convention issues that would preclude or unnecessarily limit an international tug of opportunity system.

(c) Identify salvage and operational legal constraints.

(d) Identify cabotage legal constraints associated with foreign towing vessels operating in U.S. waters.

(e) Indicate any liability coverage issues potentially affecting responders in the international tug of opportunity system.

(f) Indicate the use of any contractual relationship between the international tug of opportunity system and service recipients to further limit liability.

4. Fiscal Administration

(a) Identify the fee structure for organizational administration and incident-specific assistance services, the penalties for noncompliance, the billing process, and the method of collection.

(b) Identify the difference between member and nonmember use of services.

(c) Identify the process for reviewing service charges upon challenge.

(d) Identify the procedure for reimbursement of contractor and governmental authorities.

(e) Identify the requirements and expected methods to be used for initial capital investments.

Marine Safety Requirements

1. Tug Performance Criteria

(a) A tug of opportunity must be able to transit and maneuver in the Strait of Juan de Fuca in wave heights of 3 meters or more with sustained wind speed of greater than 20 knots (kts), and in offshore wave heights of 4 meters or more with sustained wind speeds of greater than 30 kts to get a line onto a disabled vessel.

(b) A tug of opportunity must meet the following requirements shown in the table in accordance with the wave heights listed.

Bollard Pull	Wave height
Class A >60 tons	5–6 meters.
Class B 40–59 tons	4 meters.
Class C 35–39 tons	3 meters.
Class D <35 tons	calm.

(c) The minimum speed capability for a tug of opportunity is 13 kts under calm conditions.

(d) The minimum speed capability for a tug of opportunity is 10 kts under degraded conditions with offshore wave heights of 4 meters.

(e) A tug of opportunity must provide a stable work platform in wave heights of 4 meters offshore or 3 meters in the Strait of Juan de Fuca.

2. Tug Equipment Criteria

(a) Towline and terminal gear required for towing astern must be as per 33 CFR 164.74 or equivalent standard.

(b) A tug of opportunity must provide tests and inspections for the gear required in item 2 of the documentation requirements as found in 33 CFR 164.80.

(c) A tug of opportunity must have on board a line handling winch with—brake capacity equal to 3 times the bollard pull, line pull equal to ⅓ times the bollard pull, and an abort mechanism.

(d) All required tow lines must have a minimum breaking strength equal to 5 times the bollard pull.

3. Crew Skills

(a) Manning standards for tugs and the documents and licenses required for tug crews must meet U.S. Coast Guard regulations as per 46 CFR 15.

(b) The master of a tug of opportunity shall ensure crew proficiency in emergency operations and towing operations, and identify skills which must be developed and maintained through training and exercises.

(c) The master of a tug of opportunity shall certify to the tug of opportunity system operator that the vessel has the capability to tow deep draft vessels under adverse conditions, and may be required to demonstrate that capability.

(e) The master of a tug of opportunity shall ensure that the number of trained and skilled crew members on board is sufficient to meet tug of opportunity system requirements.

4. Training

(a) Each tug of opportunity must have a training/certification program that ensures that crew members acquire and maintain the skills required to operate towing equipment. Each tug of opportunity must also document these skills.

(b) Each tug of opportunity must have an exercise program for quarterly towing drills.

5. Substance Abuse Standards

Uninspected vessels included in a tug of opportunity program must meet the drug and alcohol testing standards as described in 46 CFR 16.230.

6. Response Times

(a) The maximum response time is 2 hours for the area east of the line connecting New Dungeness Light with Discovery Light and all points north and south of these lights. This area includes those waters required for escort vessels in 33 CFR 168.40(b).

(b) The maximum response time is 2.5 hours for the area of the Strait of Juan de Fuca west of the line connecting New Dungeness Light with Discovery Light to a north and south line through the buoy position at the western end of the Strait of Juan de Fuca.

(c) The maximum response time is 6 hours from a north and south line through the buoy position at the western end of the Strait of Juan de Fuca extending in a 50-mile radius offshore.

(d) The maximum response time is 12 hours for the remainder of the Olympic Coast National Marine Sanctuary southward. The southern boundary of the area is to be avoided.

Procedural

The original notice of meeting for CGD 96–044 was published on September 12, 1996 (61 FR 48202). Attendance is open to the public. Persons wishing to make oral presentations at the meeting should notify the person listed under **FOR FURTHER INFORMATION CONTACT** no later than October 10, 1996.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

Dated: October 2, 1996.

G.N. Naccara,

Captain, U.S. Coast Guard Acting Chief, Marine Safety and Environmental Protection.

[FR Doc. 96–25661 Filed 10–4–96; 8:45 am]

BILLING CODE 4910–14–M

Federal Aviation Administration

Approval of Noise Compatibility Program; Kahului Airport, Kahului, Maui, Hawaii

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its findings on the Noise Compatibility Program submitted by the State of Hawaii, Department of Transportation under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 (Public Law 96–193) and 14 CFR Part 150. These findings are made in recognition of the description of Federal and nonfederal responsibilities in Senate Report No. 96–52 (1980). On March 4, 1996 the FAA determined that the noise exposure maps submitted by the State of Hawaii, Department of Transportation under Part 150 were in compliance with applicable requirements. On August 30, 1996, the Associate Administrator for Airports approved the Kahului Airport Noise Compatibility Program. All eight (8) of the program elements were approved. One (1) element was approved for study only and one (1) element was approved as a voluntary measure.

EFFECTIVE DATE: The effective date of the FAA's approval of the Kahului Airport noise compatibility program is August 30, 1996.

FOR FURTHER INFORMATION CONTACT: David J. Welhouse, Airport Planner, Honolulu Airports District Office, Federal Aviation Administration, Box 50244, Honolulu, Hawaii 96850–0001, Telephone: (808) 541–1243; street address: 30 Ala Moana Blvd., Room 7116. Documents reflecting this FAA action may be reviewed at this location.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA has given its overall approval to the Noise Compatibility Program for the Kahului Airport, effective August 30, 1996.

Under Section 104(a) of the Aviation Safety and Noise Abatement Act of 1979 (hereinafter referred to as ''the Act''), an airport operator who has previously submitted a Noise Exposure Map, may submit to the FAA, a Noise Compatibility Program which sets forth the measures taken or proposed by the airport operator for the reduction of existing noncompatible land uses and prevention of additional noncompatible land uses within the area covered by the Noise Exposure Maps. The Act requires such programs to be developed in consultation with interested and affected parties including local communities, government agencies, airport users, and FAA personnel.

Each airport Noise Compatibility Program developed in accordance with Federal Aviation Regulations (FAR) Part 150 is a local program, not a Federal program. The FAA does not substitute its judgment for that of the airport proprietor with respect to which measures should be recommended for action. The FAA's approval or disapproval of FAR Part 150 program recommendations is measured according to the standards expressed in Part 150 of the Act and is limited to the following determinations:

a. The Noise Compatibility Program was developed in accordance with the provisions and procedures of FAR Part 150;

b. Program measures are reasonably consistent with achieving the goals of reducing existing noncompatible land uses around the airport and preventing the introduction of additional noncompatible land uses;

c. Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types or classes of aeronautical uses, violate the terms of airport grant agreements, or intrude into areas preempted by the Federal Government; and

d. Program measures relating to the use of flight procedures can be implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of the navigable airspace and air traffic control systems, or adversely affecting other powers and responsibilities of the Administrator prescribed by law.

Specific limitations with respect to FAA's approval of an airport Noise Compatibility Program are delineated in FAR Part 150, Section 150.5. Approval is not a determination concerning the acceptability of land uses under Federal, State, or local law. Approval does not by itself constitute an FAA implementing action. A request for Federal action or approval to implement specific noise compatibility measures may be required, and an FAA decision on the request may require an environmental assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the program nor a determination that all measures covered by the program are eligible for grant-in-aid funding from the FAA. Where Federal funding is sought, requests for project grants must be submitted to the FAA Airports District Office in Honolulu, Hawaii.

The State of Hawaii, Department of Transportation submitted to the FAA on October 26, 1995, the Noise Exposure Maps, descriptions, and other documentation produced during the noise compatibility planning study conducted from January 1994 through September 1995. The Kahului Airport noise exposure maps were determined by FAA to be in compliance with applicable requirements on March 4, 1996. Notice of this determination was published in the Federal Register on March 18, 1996.

The Kahului Airport study contains a proposed Noise Compatibility Program comprised of actions designed for phased implementation by airport management and adjacent jurisdictions from the date of study completion to the year 1998. It was requested that the FAA evaluate and approve this material as a Noise Compatibility Program as described in Section 104(b) of the Act. The FAA began its review of the program on March 4, 1996 and was required by a provision of the Act to approve or disapprove the program within 180 days (other than the use of new flight procedures for noise control). Failure to approve or disapprove such program within the 180-day period shall be deemed to be an approval of such program.

The submitted program contained eight (8) proposed actions for noise mitigation on and off the airport. The FAA completed its review and determined that the procedural and substantive requirements of the Act and FAR part 150 have been satisfied. The overall program, therefore, was approved by the Associate Administrator for Airports effective August 30, 1996.

All eight (8) of the program elements were approved. One (1) element was approved for study only and one (1) element was approved as a voluntary measure. Approved program measure include: Purchase private properties within the 75 DNL contour; Provide sound attenuation for residences within the 60 to 75 DNL contours; Monitor development proposals in the Kahului Airport environs; Install and operate a noise monitoring system; and annually monitor aircraft noise levels and operations at Kahului Airport. Approved for study was the measure to formalize the informal runway use program. The clarification of an informal runway use program was approved as a voluntary measure.

These determinations are set forth in detail in a Record of Approval endorsed by the Associate Administrator for Airports on August 30, 1996. The Record of Approval, as well as other evaluation materials and the documents comprising the submittal, are available for review at the FAA office listed above and at the administrative offices of the State of Hawaii.

Issued in Hawthorne, California on September 23, 1996.

Herman C. Bliss,

Manager, Airports Division, AWP–600, Western-Pacific Region.

[FR Doc. 96–25603 Filed 10–4–96; 8:45 am]

BILLING CODE 4910–13–M

Receipt of Noise Compatibility Program and Request for Review; Springfield-Beckley Municipal Airport; Springfield, OH

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces that it is reviewing a proposed noise compatibility program that was submitted for Springfield-Beckley Municipal Airport under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 (Public Law 96–193) (hereinafter referred to as ''the Act'') and 14 CFR Part 150 by the City of Springfield, Ohio. This program was submitted subsequent to a determination by the FAA that associated noise exposure maps submitted under 14 CFR Part 150 for Springfield-Beckley Municipal Airport were in compliance with applicable requirements effective August 11, 1995. The proposed noise compatibility program will be approved or disapproved on or before March 18, 1997.

EFFECTIVE DATE: The effective date of the start of the FAA's review of the noise compatibility program is September 19, 1996. The public comment period ends November 18, 1996.

FOR FURTHER INFORMATION CONTACT: Lawrence C. King, Airports Engineer, Federal Aviation Administration, Detroit Airports District Office, Willow Run Airport, East, 8820 Beck Road, Belleville, Michigan 48111. Comments on the proposed noise compatibility program should also be submitted to the above office.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA is reviewing a proposed noise compatibility program for Springfield-Beckley Municipal Airport which will be approved or disapproved on or before March 18, 1997. This notice also announces the availability of this program for public review and comment.

An airport operator who has submitted noise exposure maps that are found by the FAA to be in compliance with the requirements of Federal Aviation Regulations (FAR) Part 150, promulgated pursuant to Title I of the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes for the reduction of existing noncompatible uses and for the prevention of the introduction of additional noncompatible uses.

The FAA has formally received the noise compatibility program for Springfield-Beckley Municipal Airport, effective on September 19, 1996. It was requested that the FAA review this material and that the noise mitigation measures, to be implemented jointly by the airport and surrounding communities, be approved as a noise compatibility program under section 104(b) of the Act. Preliminary review of the submitted material indicates that it conforms to the requirements for the submittal of noise compatibility programs, but that further review will be necessary prior to approval or disapproval of the program. The formal review period, limited by law to a maximum of 180 days, will be completed on or before March 18, 1997.

The FAA's detailed evaluation will be conducted under the provisions of 14 CFR Part 150, section 150.33. The primary considerations in the evaluation process are whether the proposed measures may reduce the level of aviation safety, create an undue burden on interstate or foreign commerce, or be reasonably consistent with obtaining the goal of reducing existing noncompatible land uses and preventing the introduction of additional noncompatible land uses.

Interested persons are invited to comment on the proposed program with specific reference to these factors. All comments, other than those properly addressed to local land use authorities, will be considered by the FAA to the extent practicable. Copies of the noise exposure maps, the FAA's evaluation of the maps, and the proposed noise compatibility program are available for examination at the following locations:

Federal Aviation Administration, Detroit Airports District Office, Willow Run Airport, East, 8820 Beck Road, Belleville, Michigan 48111

Mr. Matthew J. Kridler, Manager, City of Springfield, Springfield City Hall, 76 East High Street, Springfield, OH 45502

Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT**.

Issued in Belleville, Michigan, on September 19, 1996.

Robert H. Allen,

Acting Manager, Detroit Airports District Office, FAA Great Lakes Region.

[FR Doc. 96–25605 Filed 10–4–96; 8:45 am]

BILLING CODE 4910–13–M

Federal Railroad Administration

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System or Relief From the Requirements of Title 49 CFR Part 236

Pursuant to Title 459 CFR Part 235 and 49 U.S.C. App. 26, the following railroads have petitioned the Federal Railroad Administration (FRA) seeking approval for the discontinuance or modification of the signal system or relief from the requirements of Title 49 CFR Part 236 as detailed below.

Block Signal Application (BS–AP)–No. 3406

Applicant: Southern Pacific Lines, Mr., J.A. Turner, Engineer—Signals, Southern Pacific Building, One Market Plaza, San Francisco, California 94105.

The Southern Pacific Lines, St. Louis and Southwestern Railroad seek approval of the proposed discontinuance and removal of the automatic block signal (ABS) system, associated with the spring switch at milepost 431.5, rear Alden Bridge, Louisiana, Central Region, Midwest Division, Pine Bluff Subdivision, Shreveport Line; consisting of the discontinuance and removal of the two eastbound trailing point signals at milepost 431.5, discontinuance and removal of the two eastbound ''D'' signal at milepost 432.8, conversion of the westbound facing point signal to a switch point indicator, and retention of the ''D'' signal at milepost 429.3 as an advance switch point indicator.

The reason given for the proposed changes is that the ABS system around the spring switch is not required for train operations, and a switch point indicator will provide a better operation and be less confusing to train crews.

BS–AP–No. 3407

Applicants: Chicago, Central and Pacific Railroad, Mr. John D. McPherson, Senior Vice President—Operations, Illinois Central Railroad, 17641 Ashland Avenue, Homewood, Illinois 60430–1345.

The Chicago, Central and Pacific Railroad seeks approval of the proposed discontinuance and removal of the existing two aspect automatic train stop/automatic block signal system, on the

single main track, between Cedar Falls, Iowa, milepost 283.5 and Fort Dodge, Iowa, milepost 376.1, on the Western Division, Fort Dodge Subdivision, associated with the installation of state of the art, multi-aspect, traffic control signal (TCS) and automatic block signal (ABC) systems, utilizing electronic coded track circuits and pole line elimination, at the following locations:

- TCS .... milepost 283.5 to milepost 325.5
- ABS ... milepost 325.5 to milepost 327.7
- TCS .... milepost 327.7 to milepost 352.7
- ABS ... milepost 352.7 to milepost 355.6
- TCS .... milepost 355.6 to milepost 373.7
- ABS ... milepost 373.7 to milepost 376.1

The reasons given for the proposed changes are as follows:

1. The inability to acquire replacement parts for the functionally and technologically obsolete, two aspect, automatic train stop (ATS) system, which utilizes vacuum tube technology;

2. The existing ATS system provides only two indications, proceed and proceed at restricted speed, therefore reducing systems credibility and operation efficiency;

3. The installation of the new TCS and ABS multi-aspect systems will provide train engineers more information about braking and route integrity, thereby improving train handling, efficiency, and safety; and

4. The installation of the new systems will effectively renew all signal equipment on the territory with state of the art technology and will eliminate the existing pole line.

Any interested party desiring to protest the granting of an application shall set forth specifically the ground upon which the protest is made, and contain a concise statement of the interest of the protestant in the proceeding. The original and two copies of the protest shall be filed with the Associate Administrator for Safety, FRA, 400 Seventh Street, S.W., Washington, D.C. 20590 within 45 calendar days of the date of issuance of this notice. Additionally, one copy of the protest shall be furnished to the applicant at the address listed above.

FRA expects to be able to determine these matters without oral hearing. However, if a specific request for an oral hearing is accompanied by a showing that the party is unable to adequately present his or her position by written statements, an application may be set for public hearing.

Issued in Washington, D.C. on September 9, 1996.

Phil Olekszyk,

Acting Associate Administrator for Safety.

[FR Doc. 96–25635 Filed 10–4–96; 8:45 am]

BILLING CODE 4910–06–M

National Highway Traffic Safety Administration

[Docket No. 96–108; Notice 1]

General Motors Corporation; Receipt of Application for Decision of Inconsequential; Noncompliance

General Motors Corporation, (GM) of Warren, Michigan, has determined that certain 1996 Saturn passenger cars fail to conform to the requirements of 49 CFR 571.115, Federal Motor Vehicle Safety Standard (FMVSS)115, ''Vehicle Identification Number,'' and has filed an appropriate report pursuant to 49 CFR Part 573 ''Defect and Noncompliance Information Report.'' GM has also applied to be exempted from the notification and remedy requirements of 49 U.S.C., Section 30118 and 30120 and 49 CFR Part 556, ''Exemption for inconsequential defect or noncompliance,'' on the basis that the noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of an application is published under 49 U.S.C. 30118(d) and does not represent any agency decision or other exercise of judgment concerning the merits of the application.

Paragraph S4.6 of FMVSS No. 115 requires that the VIN for passenger cars, * * * be located inside the passenger compartment. It shall be readable, without moving any part of the vehicle through the vehicle glazing under daylight lighting conditions by an observer having 20/20 vision * * *. Each character in the VIN subject to this paragraph shall have a minimum height of 4 mm.

GM's description of the noncompliance follows: From December 1 through 31, 1995, approximately 403 Saturn, Model Year 1996 vehicles were produced which fail to comply with requirements in FMVSS No. 115. Because of a temporary deviation from the normal production process, the instrument panel upper trim cover partially obscured the lower portion of the VIN plates on 260 cars shipped to Saturn retailers. GM first became aware of this condition in January of 1996. The characters on the VIN plate are 4 millimeters high. Based on measurements of 25 cars, Saturn estimates that up to one millimeter of some characters was covered on 91.9% of the cars and more than one millimeter was covered on only 8.1% of the cars (about 22 cars). It is easy to read the VIN characters when up to one millimeter is covered.

GM supported its application for inconsequential noncompliance with the following:

''The VIN is in two other easily accessible places—the certification label on the driver's door and the service parts label on the spare tire cover (the owner's manual identifies these locations). Derivatives of the VIN also appear on the engine and transmission. Because the VIN appears in several places on these cars, as well as on the car's title and registration, these cars can be easily identified for the purpose of determining whether they are subject to [recall] campaigns.

''GM uses a 'posident style' font * * * in which each character has a unique upper and lower half. Police agencies have copies of the font sample and will be able to read the VIN even in the worst case condition (2.25 millimeters was the highest obscuration measured). Even without the aid of the font sample, a customer will likely be able to read most of the characters.

''Saturn has not received any field service reports or complaints from customers, dealers, motor vehicle registration officials, or law enforcement personnel. This indicates that no one is being seriously inconvenienced by this condition.

''The NHTSA has agreed that other comparable instances of non-compliance with FMVSS 115 were inconsequential: Marina Mobili, Inc., 51 FR 40367 (50 motorcycles with less than 17 characters in VIN); Volvo White Truck Corp., 47 FR 35063 (46 trucks with wrong model year code); General Motors Corp., 58 FR 32167 (630 cars with VIN characters smaller than 4 millimeters).

''[GM] this non-compliance is inconsequential to motor vehicle safety. A recall would impose costs on Saturn and inconvenience its customers without creating any safety benefit.''

Interested persons are invited to submit written data, views, and arguments on the application of GM, described above. Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 5109, 400 Seventh Street, SW, Washington, D.C., 20590. It is requested but not required that six copies be submitted.

All comments received before the close of business on the closing date indicated below will be considered. The application and supporting materials, and all comments received after the closing date, will also be filed and will be considered to the extent possible. When the application is granted or denied, the notice will be published in the Federal Register pursuant to the authority indicated below. Comment closing date: November 6, 1996.

(49 U.S.C. 30118, 30120; delegation of authority at 49 CFR 1.50 and 501.8)

Issued on: October 1, 1996.

L. Robert Shelton,

Associate Administrator for Safety Performance Standards.

[FR Doc. 96–25611 Filed 10–4–96; 8:45 am]

BILLING CODE 4910–59–P

Surface Transportation Board

[STB Ex Parte No. 533]

FEDERAL MARITIME COMMISSION

[Docket No. 96–04]

Noncontiguous Domestic Trade Tariffs

AGENCIES: Surface Transportation Board, Department of Transportation; Federal Maritime Commission.

ACTION: Notice.

SUMMARY: The Surface Transportation Board (STB or Board) and the Federal Maritime Commission (FMC or Commission) provide notice as to how they are implementing the provisions of the ICC Termination Act of 1995 involving tariff filing and rate reasonableness in the noncontiguous domestic trade (49 U.S.C. 13701 and 13702).[1]

EFFECTIVE DATE: October 1, 1996.

FOR FURTHER INFORMATION CONTACT: Craig Keats, Office of the General Counsel, STB, (202) 927–6046 or John Cunningham, Office of the General Counsel, FMC, (202) 523–5740. [TDD for the hearing impaired: (202) 927–5721.]

SUPPLEMENTARY INFORMATION: The ICC Termination Act of 1995, Pub. L. No. 104–88, 109 Stat. 803 (ICC Termination Act), abolished the Interstate Commerce Commission (ICC). The ICC Termination Act transferred jurisdiction over ''port to port'' operations in the noncontiguous domestic trade, which had formerly been regulated by the FMC under the Intercoastal Shipping Act, 1933 (1933 Act) (46 U.S.C. 843–848), to the Board. *See* new 49 U.S.C. 13501 and 13521 (giving the Board jurisdiction over port to port water carrier transportation in the noncontiguous domestic trade); 49 U.S.C. 13702 (requiring that, with certain exceptions, water carriers operating in the noncontiguous domestic trade file tariffs with the Board); and 49 U.S.C. 13701 (providing that water carrier services in the noncontiguous domestic trade are subject to rate regulation by the Board).

Section 2 of the ICC Termination Act states that: ''Except as otherwise provided in this Act, this Act shall take effect on January 1, 1996.'' Under section 335 of the ICC Termination Act, however, repeal of the 1933 Act, and of portions of the Shipping Act, 1916 (1916 Act), does not become effective until September 30, 1996. In light of these two statutory provisions, the two agencies, in a notice published at 61 FR 5835 (Feb. 14, 1996), found that there is some ambiguity as to whether, at least until September 30, 1996, water carriers operating in the noncontiguous domestic trade must file their tariffs at the Board or the Commission, and as to which agency would be responsible for rate regulation during this interim period. The Board and the Commission, therefore, sought public comment on how the two agencies could best administer their respective statutes during the transition period ending September 30, 1996, in a manner that would be most efficient and least disruptive to the industry and the shipping public.

Comments and/or replies were filed by 13 carriers, shippers, and government entities. Of the comments that were responsive to the questions raised, some took the position that Congress, by postponing the date on which the relevant provisions of the 1916 Act and the 1933 Act were repealed, must have intended a 9-month transition period. The majority of the commentors, however, expressed the view that, because section 33 of the 1916 Act (46 U.S.C. 832) foreclosed the FMC from regulating operations already subject to ICC (now Board) jurisdiction, the Board assumed exclusive jurisdiction over operations in the noncontiguous domestic trade as of January 1, 1996. Although one of those commentors (Caribbean Shippers' Association) asserted that all tariffs and agreements on file with the FMC must be canceled immediately, most concluded that the Board could, under delegation of authority principles, permit continued tariff filing at the FMC.

After reviewing the comments, we determined that we would monitor the way in which the industry adapted to the new statute before acting. We found that, although some carriers preferred filing electronically at the FMC, while others preferred to file on paper at the Board, there were no complaints from the shipping public that carriers were not filing their port to port tariffs. For that reason, and in light of the statutory ambiguity, we concluded that we could best facilitate the transition to exclusive Board jurisdiction by permitting carriers to continue filing at either agency, as they saw fit, until September 30, 1996. Therefore, since passage of the ICC Termination Act, each agency has recognized and respected the port to port tariffs filed at the other.

Beginning on October 1, 1996, jurisdiction over port to port transportation will clearly rest only with the Board. Therefore, as of that date, all tariffs for such services must be filed with the Board, rather than the FMC.[2] In light of the Congressional report language urging the Board ''to continue the FMC's practice of allowing carriers to file their tariffs electronically,''[3] the two agencies have worked together to permit the Board to receive tariffs filed through the FMC's Automated Tariff Filing and Information System (ATFI). Accordingly, carriers that have filed their port to port tariffs electronically with the FMC may continue to do so. Additionally, the Board will allow carriers to use the ATFI system to file their joint intermodal rate tariffs for noncontiguous domestic transportation electronically. Electronic filing, however, will not be mandatory; carriers may file their port to port and intermodal tariffs in printed form at the Board.[4]

Regulatory Flexibility Analysis

The Board and the Commission certify that this action will not have a significant impact on a substantial number of small entities. No new regulatory burdens are imposed, directly or indirectly, on such entities. The purpose of the decision is simply to facilitate the transition to a new regulatory regime.

Environmental and Energy Analysis

This action will not significantly affect either the quality of the human environment or conservation of energy resources.

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[1] The two agencies are handling this matter simultaneously.

[2] Similarly, all agreements filed with the FMC pursuant to section 15 of the 1916 Act will be subject to the antitrust laws as of that date.

[3] H.R. Rep. No. 422, 104th Cong., 1st Sess. 206 (1995).

[4] The Board is authorizing these filings by order issued in *Electronic Tariff Filing of Noncontiguous Domestic Trade Tariffs,* STB Special Tariff Authority No. 4, which is being served concurrently with this notice.

Decided: September 19, 1996.

By the Board, Chairman Morgan, Vice Chairman Simmons, and Commissioner Owen.

Vernon A. Williams,

Secretary, Surface Transportation Board.

By the Commission, Chairman Creel, Commissioners Hsu, Scroggins, and Won.

Joseph C. Polking,

Secretary, Federal Maritime Commission.

[FR Doc. 96–25617 Filed 10–4–96; 8:45 am]

BILLING CODE 4915–00–P; 6730–01–P

Surface Transportation Board [1]

[STB Finance Docket No. 32714]

Fox Valley & Western Ltd.—Trackage Rights Exemption—Union Pacific Railroad Company

Union Pacific Railroad Company (UP), a Class I railroad, has agreed to grant trackage rights to Fox Valley & Western Ltd. (FVW), a Class II railroad, over UP's line of railway: (1) Between milepost 99.5, in Granville, WI, to milepost 92.4, in Wiscona, WI; (2) from milepost 8.59, in Wiscona, WI, to milepost 13.97, near Butler, WI; and (3) from milepost 17.31M to milepost 14.50, in Butler, WI, a total distance of 15.29 miles.

The transaction is scheduled to be consummated on September 27, 1996.

The trackage rights will provide for an efficient interchange route for FVW with UP in UP's Butler Yard at Butler, WI.

As a condition to this exemption, any employees affected by the trackage rights will be protected by the conditions imposed in *Norfolk and Western Ry. Co.—Trackage Rights—BN,* 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate,* 360 I.C.C. 653 (1980).

This notice is filed under 49 CFR 1180.2(d)(7). If it 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. 32714, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Branch, 1201 Constitution Avenue, N.W., Washington, DC 20423. In addition, a copy of each pleading must be served on Janet H. Gilbert, Esq., Fox Valley & Western, Ltd., 6250 N. River Road, Suite No. 9000, Rosemont, IL 60018.

Decided: September 27, 1996.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 96–25615 Filed 10–4–96; 8:45 am]

BILLING CODE 4915–00–P

[1] The ICC Termination Act of 1995, Pub. L. No. 104–88, 109 Stat. 803, which was enacted on December 29, 1995, and took effect on January 1, 1996, abolished the Interstate Commerce Commission and transferred certain functions to the Surface Transportation Board (Board). This notice relates to functions that are subject to Board jurisdiction pursuant to 49 U.S.C. 11323–24.

[STB Finance Docket No. 33121]

RailTex, Inc.—Continuance in Control Exemption—Connecticut Southern Railroad, Inc.; Correction

The notice appearing on page 50904 in the issue of Friday, September 27, 1996, incorrectly cited the docket number as [STB Finance Docket No. 32121]. The correct docket number is shown above.

Vernon A. Williams,

Secretary.

[FR Doc. 96–25616 Filed 10–4–96; 8:45 am]

BILLING CODE 4915–00–P

Surface Transportation Board [1]

[STB Finance Docket No. 32713]

Wisconsin Central Ltd.—Trackage Rights Exemption—Union Pacific Railroad Company

Union Pacific Railroad Company (UP), a Class I railroad, has agreed to grant joint trackage rights to Wisconsin Central Ltd. (WCL), a Class II railroad, over its trackage between UP's milepost 58.95 and UP's milepost 60.55 at South Itasca, WI, a distance of 1.6 miles.

The transaction is scheduled to be consummated on September 27, 1996. The trackage rights will enable WCL to use UP's main line and wye tracks at Itasca Yard for coordination of train movements.

As a condition to this exemption, any employees affected by the trackage rights will be protected by the conditions imposed in *Norfolk and Western Ry. Co.—Trackage Rights—BN,* 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate,* 360 I.C.C. 653 (1980).

This notice is filed under 49 CFR 1180.2(d)(7). If it 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. 32713, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Branch, 1201 Constitution Avenue, N.W., Washington, DC 20423. In addition, a copy of each pleading must be served on Janet H. Gilbert, Esq., Wisconsin Central Ltd., 6250 N. River Road, Suite No. 9000, Rosemont, IL 60018.

Decided: September 27, 1996.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 96–25618 Filed 10–4–96; 8:45 am]

BILLING CODE 4915–00–P

[1] The ICC Termination Act of 1995, Pub. L. No. 104–88, 109 Stat. 803, which was enacted on December 29, 1995, and took effect on January 1, 1996, abolished the Interstate Commerce Commission and transferred certain functions to the Surface Transportation Board (Board). This notice relates to functions that are subject to Board jurisdiction pursuant to 49 U.S.C. 11323–24.

DEPARTMENT OF THE TREASURY

Office of the Deputy Assistant Secretary For Information Systems; Government Information Locator Service (GILS)

AGENCY: Office of Information Resources Management, Office of the Deputy Assistant Secretary for Information Systems, Office of the Assistant Secretary for Management/CFO, U.S. Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: The U.S. Department of the Treasury, as part of its continuing information dissemination activities, announces the establishment of the Treasury GILS. Treasury invites the general public and other Federal agencies to access information resources on the Treasury GILS. Further, in order to improve its dissemination of information and delivery of services to the public, Treasury requests that the public take this opportunity to comment on the Treasury GILS.

DATES: Electronic mail, written or telefaxed comments should be received on or before November 15, 1996, to be considered for the next major update for January 1997. Comments will be welcomed on a continuing basis after that date.

ADDRESSES: Submit comments electronically via http://www.treas.gov or via facsimile to (202) 622–1595. Written comments can be submitted to Department of the Treasury, Office of Information Resources Management,

Attention: GILS, 1425 New York Avenue, NW, Room 2110, Washington, DC 20220.

FOR FURTHER INFORMATION CONTACT: Gladys R. Myatt, Department of the Treasury, Office of Information Resources Management, Washington, D.C. 20220, (202) 622–1524 (or via gladys.myatt@treas.sprint.com).

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act (PRA) of 1995, P.L. 104–13, and the Office of Management and Budget (OMB) Bulletin 95–01 established GILS. GILS is a virtual card catalog of government information and provides a new way to identify, locate, and describe publicly available Federal information resources, including electronic information resources. GILS records identify publicly-available information resources within the U.S. Federal government, describe the information available in these resources, and assist in obtaining the actual information.

The Treasury GILS site in on the Government Printing Office (GPO) Access system, at the following Internet World Wide Web address: http://www.access.gpo.gov/su__docs/gils/gils.html

This site also contains the GILS records for 25 other Federal agencies, pointer records with links to other U.S. Federal GILS sites, and additional records designed to serve as pathways to information resources in all Cabinet-level and major independent Federal agencies.

For those without WWW access, this site can also be utilized through:

—WAIS client software.
Host: wais, access,gpo.gov
Port: 210
Database: GILS

—Telneting to swais.access.gpo.gov

—Dialing in to (202) 512–1661 (log in as guest)

Access to GILS is also provided by Federal Depository Libraries.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be used to improve the Treasury GILS. All comments will become a matter of public record. Comments should address whether the types of information resources on the Treasury GILS satisfy your needs, and if not, the types of information resources that should be included.

Dated: September 30, 1996.

Jane L. Sullivan,

Director, Office of Information Resources Management.

[FR Doc. 96–25578 Filed 10–4–96; 8:45 am]

BILLING CODE 4810–25–P

Corrections

Federal Register
Vol. 61, No. 195
Monday, October 7, 1996

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 ENERGY

Federal Energy Regulatory Commission

[Docket No. RP93–100–000; Docket Nos. RP94–208–000, RP94–87–008, RP94–122–006, RP94–169–006, RP95–195–005, RP94–249–004, RP94–260–004, RP94–305–002, and RP94–364–001; Docket Nos. RP94–222–000, RP93–151–015, RP94–39–006, RP94–202–000, and RP94–309–003; Docket Nos. RP94–298–000, and TM94–14–29–000; and Docket Nos. RP94–347–000, RP94–150–000, RP94–266–000, and RP94–384–000]

Notice Establishing Format for Oral Argument

Correction

In notice document 96–24033 appearing on page 49317 in the issue of Thursday, September 19, 1996 the Docket numbers are corrected to read as set forth above.

BILLING CODE 1505–01–D

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2663–004–MN]

Minnesota Power and Light Company; Notice of Site Visit and Scoping Meeting Pursuant to the National Environmental Policy Act of 1969

Correction

In notice document 96–23995 beginning on page 49319 in the issue of Thursday, September 19, 1996, the Project number is corrected to read as set forth above.

BILLING CODE 1505–01–D

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP96–153–000]

Southern Natural Gas Company; Notice of Environmental Site Visit for the Proposed North Alabama Pipeline Project

September 25, 1996.

Correction

In notice document 96–25044 appearing on page 51280 in the issue of Tuesday, October 1, 1996, in the second column, in the first line, the docket number should read as set forth above.

BILLING CODE 1505–01–D

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

Correction

In notice document 96–24481 beginning on page 50299 in the issue of Wednesday, September 25, 1996 make the following correction:

On page 50299, in the 3rd column, 15 lines from the bottom, the *Title* ''Policies Services Agreement'' should read ''Policing Services Agreement''.

BILLING CODE 1505–01–D

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

Agency for International Development

48 CFR Part 722

[AIDAR Notice 96–1]
RIN 0412–AA29

Miscellaneous Amendments to Acquisition Regulations; Corrections

Correction

In rule document 96–25059 beginning on page 51234 in the issue of Tuesday, October 1, 1996, make the following correction:

722.103 [Corrected]

On page 51235, in the first column, in amendatory instruction 26 to section 722.103, in the third line, insert ''722.103–71 and 722.103–72 are redesignated as'' after ''Section''.

BILLING CODE 1505–01–D

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 550

RIN 3206-AH09

Pay Under the General Schedule; Termination of Intermin Geographic Adjustments

Correction

In the correction to rule document 96–1835 published on page 50535, in the issue of Thursday, September 26, 1996, the CFR part should read as set forth above.

BILLING CODE 1505–01–D

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Parts 61, 190 and 197

[CGD 96-041]

RIN 2115-AF34

Technical Amendments; Organizational Changes; Miscellaneous Editorial Changes and Conforming Amendments

Correction

In rule document 96–24834 beginning on page 50721 in the issue of Friday, September 27, 1996, make the following corrections:

§ 61.20-17 [Corrected]

1. On page 50728 in the second column, in § 61.20-17(f)(2), in the third line, ''(G-MCO)'' should read ''(G-MOC)''.

§ 190.01-3 [Corrected]

2. On page 50735 in the second column, in § 190.01-3(a), in the fifth line, ''office'' should read ''Office''.

§ 197.510 [Corrected]

3. On page 50735 in the third column, in § 197.510(a), in the sixth line ''(G-MOS)''should read ''(G-MSO)''.

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

17 CFR Part 420

RIN: 1505-AA53

Office of the Assistant Secretary for Financial Markets; Government Securities Act Regulations: Large Position Rules

Correction

In rule document 96–23331 beginning on page 48338 in the issue of Thursday, September 12, 1996 make the following corrections:

§ 420.4 [Corrected]

1. On page 48350, in § 420.4(a)(3), in the first column, in the penultimate line ''January 21, 1997'' should read ''January 10, 1997''.

§ 420.5 [Corrected]

2. On the same page, in the third column, in § 420.5, in the last line ''March 31, 1997'' should read ''March 11, 1997''.

Appendix B to Part 420 [Corrected]

3. On page 48351, in Appendix B to Part 420, in the table, in entry 1 the blank line on the right should be preceded by ''$''.

BILLING CODE 1505–01–D

federal register

Monday
October 7, 1996

Part II

Department of Transportation

Federal Transit Administration

FTA Fiscal Year 1997 Apportionments and Allocations; Notice

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

FTA Fiscal Year 1997 Apportionments and Allocations

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice.

SUMMARY: The Department of Transportation (DOT) and Related Agencies Appropriations Act, 1997 (Pub. L. 104–205), signed into law by President Clinton on September 30, 1996, provides fiscal year 1997 appropriations for the Federal Transit Administration transit assistance programs. Based upon this Act, this Notice contains a comprehensive list of apportionments and allocations of the various transit programs.

This Notice includes the apportionment of fiscal year 1997 funds for the Urbanized Area Formula Program, the Nonurbanized Area Formula Program, the Elderly and Persons with Disabilities Program, the Capital Program for Fixed Guideway Modernization, the Metropolitan Planning Program and the State Planning and Research Program, based on the 1997 DOT Appropriations Act and Federal transit laws. This Notice also contains the allocations of funds for the New Starts and Bus categories under the Capital Program. Statutory limitations on the use of operating assistance are also included in this Notice. As in fiscal year 1996, this Notice also includes the funding level authorized by the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA) for each program.

In addition, the FTA policy regarding pre-award authority to incur project costs, as well as other pertinent information, is included in this Notice.

For the first time, for information purposes, this Notice also contains the estimated state apportionment of fiscal year 1997 funds for the Federal Highway Administration (FHWA) Metropolitan Planning Program and State Planning and Research Program.

Public Law 103–272, signed by President Clinton on July 5, 1994, codifies Federal transit laws under title 49, chapter 53, of the United States Code. This Notice uses the codified citations.

FOR FURTHER INFORMATION CONTACT: The appropriate FTA Regional Administrator for grant specific information and issues; Melton Baxter, Manager, Urbanized Area Formula Program and FTA Apportionments, Office of Resource Management and State Programs, (202) 366–2053, for general information about the Urbanized Area Formula Program (49 U.S.C. 5307), the Nonurbanized Area Formula Program (49 U.S.C. 5311), the Elderly and Persons with Disabilities Program (49 U.S.C. 5310), or the Capital Program (49 U.S.C. 5309); or Robert Stout, Director, Office of Planning Operations, (202) 366–6385, for general information concerning the Metropolitan Planning Program (49 U.S.C. 5303) and State Planning and Research Program (49 U.S.C. 5313(b)).

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  6. FTA FY 1997 section 5309 new start allocations
  7. FTA FY 1997 section 5309(m)(1)(C) bus allocations
  8. FTA FY 1997 section 5303 Metropolitan Planning Program and section 5313(b) state planning and research program
  9. FHWA FY 1997 Metropolitan Planning Program and FY 1997 State Planning and Research Program
  10. Federal Transit Administration—Unit values of data—FY 1997 formula grant apportionments

I. Codification of Federal Transit Laws

On July 5, 1994, President Clinton signed Public Law 103–272, which codifies Federal transit laws at title 49, chapter 53 of the United States Code.

The enactment of Public Law 103–272 repeals the FT Act of 1992, as amended (the Act), without substantive changes to programs. The original meaning of the Act's provisions are unchanged by this codification, even though the new Public Law 103–272 language, in some instances, differs from that of the Act. The codification now includes laws enacted through July 5, 1994. Additional provisions enacted after that date, and revisions to title 49, chapter 53, will be reflected in subsequent legislation now being considered in Congress. This Notice accordingly uses the new form of citation. Listed below are the most commonly used citations:

Subject	49 U.S.C. section
Capital Program	5309
Metropolitan Planning Program	5303
Urbanized Area Formula Program.	5307
Transit Employee Protective Certification.	5333(b)
National Transit Database	5335
Elderly and Persons with Disabilities Program.	5310
Nonurbanized Area Formula Program.	5311
Rural Transit Assistance Program (RTAP).	5311(b)(2)
State Planning and Research Program.	5313(b)

II. Background

Urbanized Area Formula Program funds are apportioned by statutory formula to urbanized areas and to the Governors to provide capital, operating and planning assistance in urbanized areas. Nonurbanized Area Formula Program funds are apportioned by statutory formula to the Governors for capital and operating assistance in nonurbanized areas. The Elderly and Persons with Disabilities Program funds are apportioned by statutory formula to the Governors to provide capital assistance to organizations providing transportation service for the elderly and persons with disabilities. Fixed Guideway Modernization Formula funds are apportioned by statutory formula to specified urbanized areas for capital improvements in rail and other fixed guideways. Funds appropriated for the Metropolitan Planning Program are apportioned by a statutory formula to the Governors for allocation by them to Metropolitan Planning Organizations (MPOs) in urbanized areas or portions thereof. Appropriated funds for the State Planning and Research Program also are apportioned to States by a statutory formula. New Start funds identified for specific projects in the 1997 DOT Appropriations Act and Bus fund allocations in the accompanying Conference Report are also included in this Notice.

III. Overview of Appropriations for Grant Programs

A. General

In fiscal year 1997, the appropriation for the Urbanized Area Formula Program and the Nonurbanized Area Formula Program is $2,093,143,761. Of this amount, 94.50 percent ($1,978,020,854) is made available to the Urbanized Area Formula Program, and 5.50 percent ($115,122,907) is made available to the Nonurbanized Area Formula Program. The other program appropriations contained in this Notice are as follows: $4,500,000 for the Rural Tra Transit Assistance Program (RTAP); $56,041,239 for the Elderly and Persons with Disabilities Program; $39,500,000 for the Metropolitan Planning Program; $8,250,000 for the State Planning and Research Program; and $1,900,000,000 for the Capital Program. Of the Capital Program amount, $760,000,000 is for Fixed Guideway Modernization, $760,000,000 is for New Starts, and $380,000,000 is for Bus.

Table 1 displays the amounts appropriated for these programs, including adjustments and final apportionment/allocation amounts. The text following this table provides a narrative explanation for the funding levels and other factors affecting these apportionments/allocations.

B. ISTEA Authorized Program Levels

As in fiscal year 1996, FTA is publishing the formula apportionment and allocation tables that compare the maximum program level proposed in the ISTEA authorization law for fiscal year 1997 and the actual program funds appropriated by Congress for fiscal year 1997. The first set of columns shows the actual appropriation as apportioned for this fiscal year, and the second set of columns shows the authorization level. The funding level available to an urbanized area or State for obligation is the appropriated amount as apportioned to the area. The authorized level does not represent funds that are actually available during the fiscal year. Rather, it reflects the maximum dollar amount authorized in ISTEA for which funds can be appropriated by Congress for a particular fiscal year.

C. Project Management Oversight

49 U.S.C. 5327 allows the Secretary of Transportation to use not more than one-half of one percent of the funds made available under the Capital Program, the Urbanized Area Formula Program, the Nonurbanized Area Formula Program, the National Capital Transportation Act, as amended, and an additional one-quarter of one percent of Capital Program funds, to contract with any person to oversee the construction of any major project under these statutory programs and to conduct safety, procurement, management and financial reviews and audits. Therefore, one-half of one percent of the funds appropriated for the Urbanized Area Formula Program, the Nonurbanized Area Formula Program and the National Capital Transportation Act, as amended, for fiscal year 1997, and three-quarters of one percent of Capital Program funds have been reserved for these purposes before apportionment of the funds.

IV. Departmental Initiatives

A. Livable Communities

The FTA developed the Livable Communities Initiative to encourage a stronger link between transit and communities. FTA is promoting the development of community-sensitive transit facilities and services in order to increase transit ridership, improve personal mobility and enhance the quality of life in communities. Active community involvement in the planning and design process is essential in developing more community-sensitive transit, and planning methods need to be more responsive to community concerns.

Community-sensitive transit is customer-friendly, community-oriented and designed to function effectively within the community. Customer-friendly transit provides readily available information, safety and security measures. Real-time customer information, monitoring devices, help zones and improved lighting are illustrative characteristics. Community-oriented transit incorporates on-site services such as child care, public safety, health care and retail conveniences. Well-designed transit, from the perspective of more livable communities, improves pedestrian access, increases the person-carrying capacity of local transportation networks, and reflects the aesthetic and historic character of communities. More community-sensitive transit may result in increased transit ridership, reduced single occupant vehicle trips and improved air quality. In fiscal year 1996, FTA awarded a number of capital grants to implement projects which reflected the characteristics of community-sensitive transit.

The Livable Communities Initiative recognizes the important role that local land use and transportation policy can play in improving the effectiveness of

transit. These are important tools in promoting transit facilities and services which help to make communities more livable. Mixed use development around transportation nodes combined with parking management, priority access for transit vehicles and transit pass programs can significantly reduce auto trips and increase transit ridership. FTA is asking transit agencies to work with local governments, employers and the business community in implementing transit-supportive land use and transportation strategies through the metropolitan planning process.

FTA urges grantees to incorporate the concepts of the Livable Communities Initiative into the planning and capital projects financed with Federal assistance identified in this Notice and funds transferred as permitted by the flexible funding provisions of ISTEA. In addition, FTA urges grantees to consider incorporating quality design and art into transit projects funded with FTA assistance. FTA Circular C9400.1A, Design and Art and Transit Projects, June 9, 1995 provides more detail on this matter.

B. Intelligent Transportation Systems

The Department of Transportation is actively promoting the development of Intelligent Transportation Systems (ITS) which apply advanced computer, communication, information and navigation technologies to surface transportation. ITS technologies improve transit operating efficiency and make transit customer-friendly and easier to use.

ITS represents a significant step in the advancement of transit technology, and demonstration projects of the past few years have proven that significant benefits are possible. These initial successes have set the stage for the broader ITS deployments being developed today. As transit ITS expands from research and demonstration to full-scale implementation, transit operators around the country are recognizing that ITS offers as much—if not more—to the transit industry as it does to other transportation modes.

ITS improves transit operational efficiency in a variety of ways. In Kansas City, Automatic Vehicle Location technology has helped the Kansas City Area Transit Authority decrease capital costs by approximately $1.8 million and operating costs by $400,000 annually. The introduction of Smart Cards in the Metropolitan Atlanta Rapid Transit Authority rail stations is estimated to save $2.4 million in annual cash handling costs. Several transit operators are also exploring the use of ITS vehicle location technology to assist with Americans with Disabilities Act (ADA) compliance by coordinating timed transfers between fixed-route and paratransit services.

ITS improves customer service in a variety of ways. For example, at bus stops: letting customers know if the bus just left or is about to arrive; on board vehicles: using in-vehicle signs and enunciator systems informing passengers of upcoming stops; at transfer points: sending hold notification to vehicles so passengers do not miss their transfers; during emergencies: using an emergency response system to direct immediate help to vehicles in distress; and at the farebox: enabling patrons to use a common fare card for all transit services in a region.

It is important that transit agencies consider the application of these ITS technologies as current planning and capital programs are developed. Authorities planning to purchase equipment such as radios, in-vehicle signs, fare boxes, passenger counters or any other electronic hardware, should consider the gains from integrating state-of-the-art technologies.

Applications of ITS technologies are enhanced if they are integrated among multiple transit agencies and with ITS traffic management systems. Traveler information systems for all customers are enhanced by providing both transit and highway information. Such systems include data which is readily and freely shared between the transit and highway ITS systems.

By integrating these systems, an ''Intelligent Transportation Infrastructure'' of technology will be created providing maximum benefits to all travelers, including those who use transit within metropolitan areas.

As requests for funding assistance are received by the FTA and other USDOT modal administrations, they will be reviewed with an intent toward ensuring that all surface transportation modes using or planning ITS systems share data to realize the fullest advantages of these systems. Metropolitan Planning Organizations, state Departments of Transportation, and transit authorities are encouraged to cooperate in the planning, design, acquisition, deployment and operation of ITS systems and to recognize the great potential of transit ITS applications. These organizations are also encouraged to ensure that transit ITS is fully integrated among transit agencies and with other ITS applications such as traffic management and traffic information systems. It is important that decision makers keep their options open in specifying and procuring ITS systems so future enhancements and modal integrations may be readily added onto systems without costly modifications.

It is critical that consideration of ITS technologies occur within the context of the planning process, which includes long range planning, regional planning studies, corridor and subarea studies (major investment studies), preliminary engineering, operations planning and management systems. These considerations should be reflected in the transportation plan, the Transportation Improvement Program, and Unified Planning Work Program. Central to this process is the identification of problems and their underlying causes so that appropriate solutions can be found. ITS strategies should be considered along with traditional alternatives which address transportation problems. In this way the costs and benefits of ITS and other strategies can be assessed so that the optimum mix of solutions can be determined.

For further information, please contact the appropriate FTA Regional Administrator.

C. ADA Paratransit Service Implementation

Reduction of Paperwork for ADA Paratransit Plan Updates. To reduce paperwork and the administrative burden of regulation, on May 21, 1996 (see 61 Federal Register 25409), the DOT amended its regulation, 49 CFR Part 37, implementing the transportation provisions of the Americans with Disabilities Act of 1990 (ADA). The DOT eliminated the annual ADA paratransit plan update submission requirement, 49 CFR Section 37.135(c), for those systems that have fully implemented ADA paratransit service. In 1996, almost all of the 530 systems report full implementation. ADA paratransit service is to be fully implemented by January 26, 1997. Full implementation means that all of the six ADA paratransit service requirements listed in Section 37.131 (service area, response time, fares, trip purpose, hours/days of service, and capacity constraints) have been met. If the transit authority has fully implemented these requirements, an annual update or progress report is no longer required. Further, the public hearing on the annual plan update is no longer required. All that is required of an FTA grantee is to complete the fiscal year 1997 Annual List of Certifications and Assurances, Category I, part G, which is an Assurance of Nondiscrimination on the Basis of Disability. However, if the ADA

paratransit service requirements will not be met by January 26, 1997, an applicant for funding must notify the appropriate FTA regional office in writing, submit a 1997 plan update to FTA by January 26, 1997, and submit a temporary time extension request to FTA to continue to remain eligible for federal funding. As of October 1, 1996, the FTA has not received any requests for a temporary time extension based on undue financial burden during the last three years.

D. Consolidated Planning Grant (CPG)

Beginning in fiscal year 1997, FTA and FHWA will offer the states the opportunity to participate in a pilot Consolidated Planning Grant (CPG) program. This concept is consistent with the American Association of State Highway and Transportation Officials policy endorsing consolidation of FHWA and FTA planning funds and with comments received from our customers during ISTEA outreach meetings.

A consolidated grant will accomplish three important goals. First, it will result in one set of grant application and reporting procedures and one billing process, thereby streamlining the program. Second, the non-mode-specific nature of a consolidated grant will enhance the multimodal approach to transportation planning envisioned in ISTEA and the joint planning regulations. Finally, as the two agencies move toward greater streamlining, the cooperative effort required for unified delivery will reduce duplication of effort and increase FHWA and FTA staff time available for customer service.

In response to suggestions to streamline and consolidate the highway and transit planning programs, FTA and FHWA will initiate a pilot program to demonstrate this consolidated grant concept and invite the states' participation in the pilot. The CPG is intended to incorporate some of the most ''customer-friendly'' aspects of the FTA and FHWA separate processes. Under this pilot, the State's FHWA Metropolitan Planning funds and, at a State's request, the planning portion of FHWA's State Planning and Research funds and other Title 23, USC funds that may be used for metropolitan and statewide planning (i.e. Minimum Allocation, Funding Restoration, National Highway System (NHS), and/or STP), would be made available to FTA, similar to the process used for flexible STP funds. For information purposes, estimates of the FHWA Metropolitan Planning funds and the FHWA State Planning and Research funds, 75% of which is available for planning, are included in Table 9. The FHWA funds would be combined with FTA's counterpart planning funds and awarded electronically as a consolidated grant through FTA's Electronic Grant Making and Management (EGMM) System. States would submit a single claim for reimbursement to FTA. FHWA/FTA oversight and administrative responsibilities will be mutually agreed to by the affected field offices. Currently, all states are connected to the FTA Grants Management Information System which supports EGMM. EGMM software, training and support are available at no cost for any state wishing to utilize EGMM to apply for and receive consolidated planning grant funds.

Both the FTA and the FHWA view this pilot as a critical element in our efforts to ''redefine government'' and provide better customer service. We will receive expressions of interest through either the FTA Regional Office or FHWA Division Office.

E. Transit-Oriented Development

FTA is encouraging local governments and transit agencies to implement transit-oriented development around transit sites. This type of development includes mixed uses, carefully managed parking and good pedestrian access, and is within easy walking distance of the transit facilities.

Transit-Oriented Development on property owned by transit agencies promotes transit use and provides a source of income for transit operations. For example, some transit agencies lease air rights or ground space at transit stations for retail centers, day care facilities or news stands. To facilitate greater opportunities for joint development at transit sites, DOT has approved individual exceptions to the Federal government's Common Grant Rule for transit agencies in Washington, D.C.; Portland, Oregon; and Atlanta, Georgia. These three pilots may now involve the sell of unneeded property for transit-oriented development on that property, and use the income for transit-related capital and operational purposes.

F. FTA Home Page on the Internet

FTA in its efforts to provide better customer service and broaden the availability of FTA information has established an FTA Home Page on the Internet. This apportionment Notice as well as FTA program circulars (Section 5309 Capital Program: Grant Application Instructions—C9300.1, September 29, 1995; Section 18 Program Guidance—9040.1C (now Section 5311 Nonurbanized Area Formula Program), November 3, 1992; Section 16 Capital Assistance Program Guidance, 9070.1C, (now Section 5310 Elderly and Persons with Disabilities Program), December 23, 1992; Grant Management Guidelines, C5010.1B, September 7, 1995; and Third Party Contracting Requirements, C4220.1D, April 15, 1996) are contained therein.

The FTA Home Page may be reached through the DOT Home Page at the following address: http://www.fta.dot.gov.

V. Urbanized Area Formula Program (49 U.S.C. 5307)

A. Total Urbanized Area Formula Apportionments

In addition to the appropriated fiscal year 1997 Urbanized Area Formula funds of $1,978,020,854, the apportionment also includes $8,031,253 in deobligated funds which have become available for reapportionment for the Urbanized Area Formula Program as provided by 49 U.S.C. 5336(i).

Table 2 displays the amount apportioned for the Urbanized Area Formula Program. After the one-half percent for project management oversight is reserved ($9,890,104), the amount appropriated for this program is $1,968,130,750. The funds to be reapportioned, described in the previous paragraph, have then been added. Thus, the total amount apportioned for this program is $1,976,162,003.

B. Data Used for Urbanized Area Formula Apportionments

Data from the 1995 National Transit Database (49 U.S.C. 5335) Report Year submitted in late 1995 and early 1996 have been used to calculate the fiscal year 1997 Urbanized Area Formula apportionments for urbanized areas 200,000 in population and over. The population and population density figures used in calculating the Urbanized Area Formula are from the 1990 Census.

C. Adjustments for Energy and Operating Efficiencies

49 U.S.C. 5336(b)(2)(E) provides that, if a recipient of Urbanized Area Formula Program funds demonstrates to the satisfaction of the Secretary that energy or operating efficiencies would be achieved by actions that reduce revenue vehicle miles but provide the same frequency of revenue service to the same number of riders, the recipient's apportionment under 49 U.S.C. 5336(b)(2)(A)(i) shall not be reduced as a result of such actions. One recipient has submitted data acceptable to FTA in

accordance with this provision. Accordingly, the revenue vehicle miles used in the Urbanized Area Formula database to calculate the fiscal year 1997 Urbanized Area Formula apportionment reflect the amount the recipient would have received without the reductions in mileage.

D. Designation of New Urbanized Area

In fiscal year 1996, Flagstaff, Arizona, was designated an urbanized area by a special census review. This newly urbanized area is included for the first time in the Arizona Governor's apportionment for urbanized areas under 200,000 in population and is no longer eligible for inclusion in Section 5311 grants obligated in fiscal year 1997 and beyond.

E. Urbanized Area Formula Fiscal Year 1997 Apportionments to Governors

The total Urbanized Area Formula apportionment to the Governor for use in areas under 200,000 in population for each State is shown on Table 2. Table 2 also contains the total apportionment amount attributable to each of the urbanized areas within the State. The Governor may determine the allocation of funds among the urbanized areas under 200,000 in population with one exception. As further discussed below in Section H, funds attributed to an urbanized area under 200,000 in population, located within the planning boundaries of a transportation management area, must be obligated in that area.

F. Urbanized Area Formula Operating Assistance Limitations

The fiscal year 1997 limitations on the amount of Urbanized Area Formula funds that may be used for operating assistance are shown on Table 2 with the fiscal year 1997 apportionment.

The operating assistance limitations for all urbanized areas have been adjusted by 49 U.S.C. 5336(d)(2) to reflect the increase in the Consumer Price Index (CPI) for all urban consumers during the most recent calendar years. *The CPI Detailed Report,* December 1995, published by the Department of Labor (DOL), establishes that the calendar year 1995 CPI increase for all urban consumers is 2.5 percent. This increase was applied against the base operating assistance limitation calculated in accordance with 49 U.S.C. 5336(d)(2). In addition, Flagstaff, Arizona, the new urbanized area designated by special census, has been given an operating assistance limitation of two-thirds of its apportionment, consistent with the provision of 49 U.S.C. 5336(d)(1).

These adjustments result in an overall national fiscal year 1997 authorized operating assistance limitation level of $1,140,989,706. However, the 1997 DOT Appropriations Act limits the nationwide availability for operating assistance to a maximum of $400,000,000. Further, it maintains the level of transit operating assistance to urbanized areas of less than 200,000 in population at seventy-five percent of the amount of operating assistance such areas received in fiscal year 1995. Accordingly, the operating assistance limitation published in this Notice takes into account both the 1997 DOT Appropriations Act and Federal transit laws. Therefore, the higher operating assistance limitation as authorized under Federal transit laws ($1,140,990,224) was reduced to the $400,000,000 required by the 1997 DOT Appropriations Act by taking a pro rata reduction across all categories of grantees. Further, the operating assistance limitation to urbanized areas less than 200,000 in population was adjusted to $92,949,803 or seventy-five percent of the amount of their fiscal year 1995 level of $123,933,070. The operating assistance limitation of $85,791 for Flagstaff, Arizona (a newly designated urbanized area) was then added, thereby increasing the fiscal year 1997 level for these areas to $93,035,594. The remaining $306,964,406 of the $400,000,000 was prorated to urbanized areas above 200,000 in population, as authorized by the 1997 DOT Appropriations Act.

Consistent with the 1997 Conference Report, the Secretary hereby directs each area of 1,000,000 or more in population to give priority consideration to the impact of reductions in operating assistance on smaller transit authorities operating within the area, and to consider the needs and resources of such transit authorities when the limitation is distributed among all transit authorities operating in the area.

G. Statewide Operating Assistance Limitations

49 U.S.C. 5307(f) specifies that in any case in which a statewide agency or instrumentality is responsible under State laws for the financing, construction and operation, directly, by lease, contract or otherwise, of public transportation services, and when such statewide agency or instrumentality is the designated recipient of FTA funds, and when the statewide agency or instrumentality provides service among two or more urbanized areas, the statewide agency or instrumentality shall be allowed to apply for operating assistance up to the combined total permissible amount of all urbanized areas in which it provides service, regardless of whether the amount for any particular urbanized area is exceeded. However, the amount of operating assistance provided for another State or local transportation agency within the affected urbanized areas may not be reduced.

H. Designated Transportation Management Areas

All urbanized areas over 200,000 in population have been designated as transportation management areas (TMAs), in accordance with 49 U.S.C. 5305. These designations were formally made in a Federal Register Notice dated May 18, 1992 (57 FR 21160), signed by the Federal Highway Administrator and the Federal Transit Administrator. Additional areas may be designated as TMAs upon the request of the Governor and the MPO designated for such area or the affected local officials. As of October 1, 1996, two additional TMAs have been formally designated: Petersburg, Virginia, comprised solely of the Petersburg, Virginia, urbanized area; and Santa Barbara, Santa Maria, and Lompoc, California, which were combined and designated as one TMA.

Guidance for setting the boundaries of TMAs is contained in the joint transportation planning regulations codified at 23 CFR part 450 and 49 CFR part 613. In some cases, the TMA boundaries which have been established by the MPO for the designated TMA also include one or more urbanized areas with less than 200,000 in population. Where this situation exists, the discretion of the Governor to allocate urbanized area formula program ''Governor's Apportionment'' funds for urbanized areas with less than 200,000 in population is restricted.

As required by 49 U.S.C. 5307(a)(2), a recipient(s) must be designated to dispense the Urbanized Area Formula funds attributable to TMAs. Those urbanized areas that do not already have a designated recipient must name one and notify the appropriate FTA regional office of the designation. This would include those urbanized areas with less than 200,000 in population that may receive TMA designation independently, or those with less than 200,000 in population which are currently included within the boundaries of a larger designated TMA. In both cases, the Governor would only have discretion to allocate Governor's Apportionment funds attributable to areas which are outside of designated TMA boundaries. In order for the FTA and Governors to know which

urbanized areas under 200,000 in population are included within the boundaries of an existing TMA, and so that they can be identified in future Federal Register notices, each MPO whose TMA planning boundaries include these smaller urbanized areas is asked to identify such areas to the FTA. This notification should be made in writing to the Associate Administrator for Program Management, Federal Transit Administration, 400 7th Street, SW., Washington, DC 20590, no later than July 1 of each fiscal year. To date, FTA has been notified of the following urbanized areas with less than 200,000 in population that are included within the planning boundaries of designated TMAs:

Designated TMA	Small urbanized area included in TMA boundaries
Baltimore, Maryland	Annapolis, Maryland.
Dallas-Fort Worth, Texas	Denton, Texas, Lewisville, Texas.
Houston, Texas	Galveston, Texas, Texas City, Texas.
Philadelphia, Pennsylvania	Pottstown, Pennsylvania.
Pittsburgh, Pennsylvania	Monessen, Pennsylvania Steubenville-Weirton, OH–WV–PA (PA portion).
Seattle, Washington	Bremerton, Washington.
Washington, DC–MD–VA	Frederick, Maryland (MD portion).

I. Urbanized Area Formula Funds Used for Highway Purposes

Urbanized Area Formula funds apportioned to a TMA, except for those amounts which can be used for the payment of operating expenses, are also available for highway projects if the following three conditions are met: (1) such use must be approved by the MPO after appropriate notice and opportunity for comment and appeal are provided to affected transit providers; (2) in the determination of the Secretary, such funds are not needed for investments required by the Americans with Disabilities Act (ADA) of 1990; and (3) funds may be available for highway projects under title 23, U.S.C., only if funds used for the State or local share of such highway projects are eligible to fund either highway or transit projects.

Urbanized Area Formula funds which are designated for highway projects will be transferred to and administered by the Federal Highway Administration (FHWA). The MPO should notify FTA of its intent to program FTA funds for highway purposes.

VI. Nonurbanized Area Formula Program (49 U.S.C. 5311) and Rural Transit Assistance Program (RTAP) (49 U.S.C. 5311(b)(2))

A. Nonurbanized Area Formula Program

The fiscal year 1997 Nonurbanized Area Formula apportionments to the states totaling $116,158,383 are displayed in Table 3. Of the $115,122,907 appropriated, one-half percent ($575,615) was reserved for project management oversight. In addition to the current appropriation, the funds available for apportionment included $1,611,091 consisting of deobligated funds from fiscal years prior to 1994.

The population figures used in calculating these apportionments are from the 1990 Census. The database for the State of Arizona has been adjusted to account for Flagstaff, Arizona, a newly designated urbanized area that is no longer eligible for Nonurbanized Area Formula grants.

The Nonurbanized Formula Program provides capital, operating and administrative assistance for areas less than 50,000 in population. Each State must spend no less than 15 percent of its fiscal year 1997 Nonurbanized Area Formula apportionment for the development and support of intercity bus transportation, unless the Governor certifies to the Secretary that the intercity bus service needs of the State are being adequately met. Fiscal year 1997 Nonurbanized Area Formula grant applications must reflect this level of programming for intercity bus or include a certification from the Governor.

B. Rural Transit Assistance Program (RTAP)

The fiscal year 1997 RTAP allocations to the States totaling $4,566,568 are also displayed on Table 3. This amount includes $4,500,000 in fiscal year 1997 appropriated funds, and $66,568 in prior year deobligated funds which have become available for reallocation for this program. The funds are allocated to the States to undertake research, training, technical assistance, and other support services to meet the needs of transit operators in nonurbanized areas. These funds are to be used in conjunction with the States' administration of the Nonurbanized Area Formula Program.

VII. Elderly and Persons With Disabilities Program (49 U.S.C. 5310)

A total of $56,059,007 is apportioned to the States for fiscal year 1997 for the Elderly and Persons with Disabilities Program. In addition to the fiscal year 1997 appropriation of $56,041,239 the fiscal year 1997 apportionment also includes $17,768 in prior year unobligated funds which have become available for reapportionment for the Elderly and Persons with Disabilities Program. Table 4 shows each State's apportionment.

The formula for apportioning these funds uses 1990 Census population data for persons aged sixty-five and over and for persons with disabilities.

The funds provide capital assistance for transportation for elderly persons and persons with disabilities. Eligible capital expenses may include, at the option of the recipient, the acquisition of transportation services by a contract, lease, or other arrangement.

While the assistance is intended primarily for private non-profit organizations, public bodies that coordinate services for the elderly and persons with disabilities, or any public body that certifies to the State that non-profit organizations in the area are not readily available to carry out the service, may receive these funds.

These funds may be transferred by the Governor to supplement the Urbanized Area Formula or Nonurbanized Area Formula capital funds during the last 90 days of the fiscal year.

VIII. Surface Transportation Program ''Flexible'' Funds Used for Transit Purposes (Title 23, U.S.C.)

A. Transfer Process

''Flexible'' DOT funds, such as Surface Transportation Program (STP) funds, Congestion Mitigation and Air Quality (CMAQ) funds, or others, which are designated for use in transit projects, are transferred from the FHWA to FTA after which FTA approves the project and awards a grant. Flexible funds designated for transit projects must result from the local and state planning and programming process, and must be included in an approved State Transportation Improvement Program

(STIP) before the funds can be transferred. In order to initiate the transfer process, the grantee must submit a completed application to the FTA Regional Office, and must notify the state highway/transportation agency that it has submitted an application which requires a transfer of funds. Once the state highway/transportation agency determines that the state has sufficient obligation authority, the State agency notifies FHWA that the funds are to be used for transit purposes and requests that the funds be obligated by FHWA as a transfer project to FTA. The flexible funds transferred to FTA will be placed in an urbanized area or state account for one of the three existing formula programs—Urbanized Area, Elderly and Persons with Disabilities, or Nonurbanized Area.

The flexible funds are then treated as FTA formula funds, although they retain a special identifying code. They may be used for any purpose eligible under these FTA programs except for operating expenses. All FTA requirements are applicable to transferred funds. Flexible funds should be combined with regular FTA formula funds in a single annual grant application.

B. Matching Share for Flexible Funds

The provisions of Title 23, U.S.C. regarding the non-Federal share apply to Title 23 funds used for transit projects. Thus, flexible funds transferred to FTA retain the same matching share that the funds would have if used for highway purposes and administered by the FHWA.

There are three instances in which a higher than 80 percent Federal share would be maintained. First, in States with large areas of Indian and certain public domain lands, and National Forests, parks and monuments, the local share for highway projects is determined by a sliding scale rate, calculated based on the percentage of public lands within that state. This sliding scale, which permits a greater Federal share, but not to exceed 95 percent, is applicable to transit projects funded with flexible funds in these public land states. FHWA develops the sliding scale matching ratios for the increased Federal share.

Secondly, commuter carpooling and vanpooling projects and transit safety projects using flexible funds administered by FTA may retain the same 100 percent Federal share that would be allowed for ride-sharing or safety projects administered by the FHWA. The third instance includes the 100 percent Federal safety projects; however, these are subject to a nationwide ten percent program limitation.

C. Other Funds Transferred to FTA

Certain demonstration projects authorized in Title 23 are specified to be used for transit projects and are more appropriately administered by FTA. In such cases, FHWA has transferred the funds to FTA for administration. Since these funds are not STP flexible funds, they are transferred into the appropriate Capital Program category (Bus, New Starts, or Fixed Guideway Modernization) for obligation and are administered as Capital projects.

IX. Capital Program (49 U.S.C. 5309)

A. Fixed Guideway Modernization

Fixed Guideway Modernization funds are allocated by formula. Statutory percentages were established to allocate the first $497,700,000 to 11 fixed guideway areas. The next $70,000,000 is allocated one-half to these 11 urbanized areas and one-half to other urbanized areas with fixed guideways which are at least seven years old on the basis of the Urbanized Area Formula Program fixed guideway tier formula factors. The remaining funds are allocated to all of these urbanized areas as one universe. For fiscal year 1997, $760,000,000 was appropriated for fixed guideway modernization. After deducting the three-quarter percent for oversight ($5,700,000), $754,300,000 is available for apportionment to the specified urbanized areas for Fixed Guideway Modernization funding.

Table 5 displays these apportionments. Fixed Guideway Modernization funds apportioned for this section must be used for capital projects to modernize or improve fixed guideway systems.

All urbanized areas with fixed guideway systems that are at least seven years old are eligible to receive Fixed Guideway Modernization funds. A request for the start-up service dates for fixed guideways has been incorporated into the National Transit Database reporting system to ensure that all eligible fixed guideway data is included in the calculation of these apportionments. A threshold level of more than one mile of fixed guideway is required to receive Fixed Guideway Modernization funds. Therefore, urbanized areas reporting one mile or less of fixed guideway mileage under the National Transit Database are not included.

B. New Starts

The fiscal year 1997 appropriation for New Starts is 760,000,000. In addition, Congress reprogrammed $56,956,000 in unobligated New Starts funds originally appropriated in fiscal years 1992 and 1995, yielding an overall total of $816,956,000. This entire amount was allocated to projects specified in the 1997 DOT Appropriations Act. After applying the three-quarter percent reduction to the appropriated amount ($760,000,000) for project management oversight, $811,256,000 remains available for allocation. The amount of the project management oversight reduction ($5,700,000) is subtracted on a prorata basis from all 54 projects specified in the 1997 legislation. The final allocation for these projects is contained in Table 6 of this Federal Register Notice. Also provided in the table are prior year unobligated allocations for New Starts.

C. Bus

The fiscal year 1997 appropriation for Bus is $380,000,000 for the purchase of buses, bus-related equipment and paratransit vehicles, and for the construction of bus-related facilities. After deducting the three-quarter percent for oversight ($2,850,000), $377,150,000 remains available for projects. The Conference Report accompanying the 1997 DOT Appropriations Act earmarked all of the fiscal year 1997 Bus funds to specified states or localities for bus and bus-related projects. In three instances where funds were earmarked to States, the funds were further suballocated to local entities within these states. The Conference Report also includes the multi-year ISTEA earmarks.

Because the three-quarter percent for project management oversight was subtracted from the amount appropriated, each bus project identified in the Conference Report receives three-quarter percent less than the funding level contained in the report. No funds remain available for discretionary allocation by the Federal Transit Administrator. Table 7 displays the allocations of the fiscal year 1997 Bus funds by area and also shows prior year unobligated earmarks for the Bus Program.

X. Unit Values of Data for the Section 5307 Urbanized Area Formula, Section 5311 Nonurbanized Area Formula Programs, and Section 5309(m)(1)(A) Fixed Guideway Modernization Formula

For technical assistance purposes, the dollar unit values of data derived from the computations of the Urbanized Area Formula and Nonurbanized Area Formula Programs, and the Fixed Guideway Modernization Formula

apportionments are included in this Notice on Table 10. To determine how a particular apportionment amount was developed, areas may multiply their population, population density, and data from the National Transit Database by these unit values.

XI. Metropolitan Planning Program (49 U.S.C. 5303) and State Planning and Research Program (49 U.S.C. 5313(b))

A. Metropolitan Planning Urbanized Area Program

The fiscal year 1997 Metropolitan Planning apportionments to States for MPOs to be used in urbanized areas total $40,172,643. This amount includes $39,500,000 in fiscal year 1997 apportioned funds, and $672,643 in prior year deobligated funds which have become available for reallocation for this program. A basic allocation of 80 percent of this amount $32,138,114 is distributed to the States based on the State's urbanized area population for subsequent State distribution to each urbanized area, or parts thereof, within each State. A supplemental allocation of the remaining 20 percent $8,034,529 is also provided to the States based on an FTA administrative formula to address planning needs in the larger, more complex urbanized areas. Table 8 contains the final State apportionments for the combined basic and supplemental allocations. Each State, in cooperation with the MPOs, must develop an allocation formula for the combined apportionment which distributes these funds to MPOs representing urbanized areas, or parts thereof, within the State. This formula, which must be approved by the FTA, must ensure to the maximum extent practicable that no MPO is allocated less than the amount it received by administrative formula under the Metropolitan Planning Program in fiscal year 1991 (minimum MPO allocation). Each State formula must include a provision for the minimum MPO allocation. Where the State and MPOs desire to use a new formula not previously approved by FTA, it must be submitted to the appropriate FTA Regional Office for prior approval.

B. State Planning and Research Program

The fiscal year 1997 apportionments for the State Planning and Research Program total $8,279,228. This amount includes $8,250,000 in fiscal year 1997 apportioned funds, and $29,228 in prior year deobligated funds which have become available for reallocation to this program. Final State apportionments for this program are also contained on Table 8. This is the sixth year of a consolidated program which is apportioned to the States for the purpose of such activities as planning, technical studies and assistance, demonstrations, management training and cooperative research. In addition, a State may authorize a portion of these funds to be used to supplement planning funds allocated by the State to its urbanized areas as the State deems appropriate.

C. Data Used for Metropolitan Planning and State Planning and Research Apportionments

Population data from the 1990 Census is used in calculating these apportionments. The Metropolitan Planning funding provided to urbanized areas in each State by administrative formula in fiscal year 1991 was used as a ''hold harmless'' base in calculating funding to each State.

D. FHWA Metropolitan Planning Program and State Planning and Research Program

For information purposes, the estimated State apportionments for the FHWA Metropolitan Planning Program and State Planning and Research Program are contained in Table 9.

E. Planning Emphasis Areas (PEAs)

The PEAs are aids to the States and MPOs in the development of planning work programs. They are advisory and are intended to serve FTA, FHWA, and the rest of the Department as a means of helping to meet national transportation needs and implementing national transportation policy. The last PEAs were issued by the FTA and the FHWA on July 11, 1994. These remain in effect until changed, which is expected some time during early fiscal year 1997.

The PEAs currently under development will highlight program objectives identified jointly by FTA and FHWA including, but not limited to: ITS, multimodalism, innovative services, innovative financing, partnering, and the need for community sensitive transportation planning that considers social, environmental, economic, land-use and other quality of life factors early in the development process.

XII. Period of Availability of Funds

The funds apportioned under the Urbanized Area Formula Program, Fixed Guideway Modernization Formula, Metropolitan Planning and State Planning and Research Programs in this Notice will remain available to be obligated by FTA to recipients for three (3) fiscal years following fiscal year 1997. Any of these apportioned funds unobligated at the close of business on September 30, 2000, will revert to FTA for reapportionment under these respective programs. Funds apportioned to nonurbanized areas under the Nonurbanized Area Formula Program, including RTAP funds, will remain available for two (2) fiscal years following fiscal year 1997. Any such funds remaining unobligated at the close of business on September 30, 1999, will revert to FTA for reapportionment among the States under the Nonurbanized Area Formula Program. Funds allocated to States under the Elderly and Persons with Disabilities Program in this Notice must be obligated by September 30, 1997. Any such funds remaining unobligated as of this date will revert to FTA for reapportionment among the States under the Elderly and Persons with Disabilities Program. The 1996 DOT Appropriations Act includes a provision requiring that fiscal year 1996 New Starts and Bus funds not obligated for their original purpose as of September 30, 1998, shall be made available for other discretionary projects within the respective categories of the Capital Program. Similar provisions in the 1994 and 1995 DOT Appropriations Acts required that fiscal year 1994 Bus and New Start funds that are not obligated by September 30, 1996, shall also be made available for other discretionary Bus or New Start projects, respectively, and fiscal year 1995 Bus and New Start funds unobligated by September 30, 1997, shall be made available for other discretionary Bus or New Start projects, respectively.

XIII. Notice of Pre-Award Authority To Incur Project Cost

A. Background

FTA is engaged in an ongoing effort to streamline and simplify the administration of its programs. To this end, the agency expanded the authority extended to grantees to incur costs for operating assistance projects prior to grant award to cover planning and capital costs as well. In fiscal year 1994 FTA extended this authority to non-operating projects funded with current year apportioned formula funds. This automatic pre-award spending authority permitted a grantee to incur costs on an eligible transit capital or planning project without prejudice to possible future Federal participation in the cost of the project or projects.

B. Current Coverage

In fiscal year 1997, authority to incur costs for Fixed Guideway Modernization Formula, Metropolitan

Planning, Urbanized Area Formula, Elderly and Persons with Disabilities, Nonurbanized Area Formula, and State Planning and Research in advance of possible future Federal participation applies to fiscal year 1997 FTA funds apportioned in this Notice for the programs listed above. Carryover amounts for these programs are also included in this authority. This pre-award authority is also extended to projects intended to be funded with STP or CMAQ funds transferred to FTA in fiscal year 1997, provided that the projects are included in a Federally approved STIP. Pre-award authority applies to flexible funds prior to transfer to FTA if the conditions below are met. This pre-award authority also applies to Capital Bus funds identified in this Notice. The pre-award authority does not apply to Capital New Start funds.

C. Conditions

Similar to the FTA Letter of No Prejudice (LONP) authority, the conditions under which this authority may be utilized are specified below:

(1) This pre-award authority is not a legal or moral commitment that the project(s) will be approved for FTA assistance or that the FTA will obligate Federal funds. Furthermore, it is not a legal or moral commitment that all items undertaken by the applicant will be eligible for inclusion in the project(s).

(2) All FTA statutory, procedural, and contractual requirements must be met.

(3) No action will be taken by the grantee which prejudices the legal and administrative findings which the Federal Transit Administrator must make in order to approve a project.

(4) Local funds expended by the grantee pursuant to and after the date of this authority will be eligible for credit toward local match or reimbursement if the FTA later makes a grant for the project(s) or project amendment(s).

(5) The Federal amount of any future FTA assistance to the grantee for the project will be determined on the basis of the overall scope of activities and the prevailing statutory provisions with respect to the Federal-local match ratio at the time the funds are obligated.

(6). For funds to which this authority applies, the authority expires with the lapsing of fiscal year 1997 funds.

D. Environmental and Other Requirements

FTA emphasizes that all of the Federal grant requirements must be met for the project to remain eligible for Federal funding. Some of these requirements must be met before pre-award costs are incurred, notably the requirements of the National Environmental Policy Act (NEPA). Compliance with NEPA and other environmental laws or executive orders (e.g., protection of parklands, wetlands, historic properties) must be completed *before* state or local funds are advanced for a project expected to be subsequently funded with FTA funds. Depending on which class the project is included under in FTA's environmental regulations (23 CFR part 771) the grantee may not advance the project beyond planning and preliminary engineering before FTA has approved either a categorical exclusion (refer to 23 CFR 771.117(d)), a finding of no significant impact, or a final environmental impact statement. The conformity requirements of the Clean Air Act (40 CFR part 51) also must be fully met before the project may be advanced with non-Federal funds.

Similarly, the requirement that a project be included in a transportation improvement program, Federal procurement procedures, as well as the whole range of Federal requirements, must be followed for projects in which Federal funding will be sought in the future. Failure to follow any such requirements could make the project ineligible for Federal funding. In short, this increased administrative flexibility requires a grantee to make certain that no Federal requirements are circumvented thereby. If a grantee has questions or concerns regarding the environmental requirements, or any other Federal requirements that must be met before incurring costs, it should contact the appropriate regional office.

Before an applicant may incur costs either for activities expected to be funded by New Start funds, or for activities requiring funding beyond fiscal year 1997, it must first obtain a written LONP from the FTA. To obtain an LONP, a grantee must submit a written request accompanied by adequate information and justification to the appropriate FTA regional office.

XIV. Electronic Grant Making and Management Initiatives: Fiscal Year 1997 and Beyond

A. Background

As a result of the National Performance Review and the FTA strategic planning process, the FTA will continue to implement a series of automation improvements in the planning, development, grant making and management process which are designed to improve customer service and efficiency of program delivery. Known as the Electronic Grant Making and Management (EGMM) initiative, steps are underway to provide a streamlined graphic user interface between grantees and FTA which will allow complete electronic application submission, review, approval, and management of all grants. The ultimate goal is to have in place a fully electronic, user-friendly, paperless process for awarding and managing Federal transit assistance programs involving grants and cooperative agreements.

B. On-Line Grantee Program

The On-Line Grantee Program enables grantee agencies to access the FTA Grants Management Information System (GMIS) data base via a toll free telephone connection. With this access grantee agencies can inquire about grant and fund status, file required financial and narrative grant status reports and make annual certifications and assurances through GMIS. Over 480 of FTA's approximately 700 grantees are currently ''on-line''.

C. Electronic Grant Making and Management (EGMM)

This initiative streamlines the entire FTA grant making and management process through a paperless electronic grant application, review, approval, acceptance and management process. During Fiscal Year 1996, 34 grantee agencies participated in the FTA EGMM program. These grantees utilized EGMM to electronically develop, submit, and manage their grants during the full life cycle of the grant via grantee computer station connections to the FTA GMIS computer using a modem and a toll free telephone connection. Any agency interested in participating in the EGMM program should contact the appropriate FTA Regional Office.

D. Electronic Signature of Certifications and Assurances

The FTA is required by U.S.C. 5307 as well as other laws and regulations to obtain specific certifications and assurances for its programs. Annually, since fiscal year 1995, FTA compiled the certifications and assurances applicable to the FTA programs into one document published in the Federal Register. Grantees are able to sign one document annually certifying to all the certifications and assurances applicable to FTA grants. During fiscal year 1997, we encourage all EGMM grantee participants and on-line grantee participants to provide this certification electronically, completely eliminating paper certification.

E. Future EGMM Activities

There are two initiatives in the development stages that FTA hopes will

result in more efficient and effective customer service.

(1) The FTA is working with the FHWA to develop single agency delivery of metropolitan and state planning funds utilizing the FTA EGMM grant delivery system. FTA and FHWA will pilot test the concept of a consolidated planning grant during fiscal year 1997.

(2) FTA has contracted for the development of graphic user interface software in order to make interface with the EGMM system more user friendly.

We appreciate and look forward to the continued support of our grantees agencies as we seek additional ways to improve delivery of the transit program.

XV. Quarterly Approval of Grants

The FTA has established a quarterly approval and release cycle for processing grants. All Urbanized Area Formula, Nonurbanized Area Formula, Elderly and Persons with Disabilities, Capital, Metropolitan Planning, and State Planning and Research grants are processed on a quarterly basis. This includes grants using STP or CMAQ funds.

If completed applications are submitted to the appropriate FTA Regional Office no later than the first business day of the quarter, FTA will award grants by the last business day of the quarter.

In order to expedite the grant approval process within the quarterly approval structure, grants which are complete and have received the required Transit Employee Protective Certification from the Department of Labor (DOL) will be approved before the end of the quarter. There are only two factors which would delay FTA approval of the project beyond the end of a quarter. First is a failure by DOL to issue a Transit Employee Protective Certification where such certification is a prerequisite to a grant approval, and second is the failure of FHWA to actually transfer flexible funds.

For an application to be considered complete, all required activities such as inclusion of the project in a locally approved Transportation Improvement Program (TIP), a Federally approved State Transportation Improvement Program (STIP), intergovernmental reviews, environmental reviews, all applicable civil rights, anti-drug, clean air requirements and submission of all requisite certifications and documentation must be completed. The application must be in approvable form with all required documentation and submissions on hand, except for the labor protection certification which is issued by DOL. Incomplete applications will not be processed, but if the missing components are supplied, applications will be considered in the next quarter.

It is the policy of FTA to expedite grant application reviews and speed program delivery by reducing the number of grant applications. To this end, FTA strongly encourages grant applicants to submit only one application per fiscal year for each formula program. The single application should contain the fiscal year's capital (including flexible funds), planning and operating elements.

Applications for the first quarter should be submitted to the FTA Regional Office within five business days of this Notice. The first-quarter grants will be released on or before December 30, 1996.

XVI. Grant Application Procedures

All applications for FTA funds should be submitted to the appropriate FTA Regional Office. Formula grant applications should be prepared in conformance with the following FTA Circulars: Urbanized Area Formula—C9030.1A, September 18, 1987; Nonurbanized Area Formula—C9040.1C, November 3, 1992; Elderly and Persons with Disabilities—C9070.1C, December 23, 1992; and Section 5309 Capital Program: Grant Application Instructions—C9300.1, September 29, 1995. Applications for STP ''flexible'' fund grants should be prepared in the same manner as the apportioned funds under the Urbanized Area Formula, Nonurbanized Area Formula, or Elderly and Persons with Disabilities Programs. Guidance on preparation of applications for Metropolitan Planning, and State Planning and Research funds may be obtained from each FTA Regional Office. Also available are revised editions of the Grant Management Guidelines, C5010.1B, September 7, 1995; and Third Party Contracting Requirements, C4220.1D, April 15, 1996. Copies of circulars are available from FTA Regional Offices. Circulars are also available on the FTA Home Page on the Internet.

Issued on: September 30, 1996.

Gordon J. Linton,

Administrator.

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TABLE 1

FEDERAL TRANSIT ADMINISTRATION

FY 1997 APPROPRIATIONS AND ISTEA AUTHORIZATIONS FOR GRANT PROGRAMS

SOURCES OF FUNDS	FY 1997 APPROPRIATIONS	*AUTHORIZED LEVELS*
SECTION 5307 URBANIZED AREA FORMULA PROGRAM AND SECTION 5311 NONURBANIZED AREA FORMULA PROGRAM	$2,093,143,761	$3,958,750,000
SECTION 5307 URBANIZED AREA FORMULA PROGRAM	$1,978,020,854	*$3,741,018,750*
94.5% of Total Available for Urbanized Area Formula and Nonurbanized Area Formula Programs		
Less Oversight (1/2%)	(9,890,104)	
Reapportioned Funds Added	8,031,253	
Total Apportioned	$1,976,162,003	
Operating Assistance Limitation	$400,000,000	*$1,112,922,445*
SECTION 5311 NONURBANIZED AREA FORMULA PROGRAM	$115,122,907	*$217,731,250*
5.5% of Total Available for Urbanized Area Formula and Nonurbanized Area Formula Programs		
Less Oversight (1/2%)	(575,615)	
Reapportioned Funds Added	1,611,091	
Total Apportioned	$116,158,383	
SECTION 5311(b) RTAP PROGRAM	$4,500,000	*$10,875,000*
Reapportioned Funds Added	66,568	
Total Apportioned	$4,566,568	
SECTION 5310 ELDERLY AND PERSONS WITH DISABILITIES PROGRAM	$56,041,239	*$97,150,000*
Reapportioned Funds Added	17,768	
Total Apportioned	$56,059,007	
SECTION 5309 CAPITAL PROGRAM	$1,900,000,000	*$2,900,000,000*
SECTION 5309(m)(1)(A) FIXED GUIDEWAY MODERNIZATION	$760,000,000	*$1,160,000,000*
Less Oversight (3/4%)	(5,700,000)	
Total Apportioned	$754,300,000	
SECTION 5309(m)(1)(B) NEW STARTS	$760,000,000	*$1,160,000,000*
Less Oversight (3/4%)	(5,700,000)	
Reprogrammed Funds	56,956,000	
Total Allocated	$811,256,000	
SECTION 5309(m)(1)(C) BUS	$380,000,000	*$580,000,000*
Less Oversight (3/4%)	(2,850,000)	
Total Allocated	$377,150,000	
SECTION 5303 METROPOLITAN PLANNING PROGRAM	$39,500,000	*$97,875,000*
Reapportioned Funds Added	672,643	
Total Apportioned	$40,172,643	
SECTION 5313(b) STATE PLANNING AND RESEARCH PROGRAM	$8,250,000	*$21,000,000*
Reapportioned Funds Added	29,228	
Total Apportioned	$8,279,228	
TOTAL APPROPRIATIONS (Above Grant Programs)	$4,101,435,000	*$7,085,650,000*

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TABLE 2

FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS AND ISTEA AUTHORIZED LEVELS

URBANIZED AREA/STATE	FY 1997 SECTION 5307 APPORTIONMENT	FY 1997 OPERATING ASSISTANCE LIMITATION	*ISTEA FY 1997 AUTHORIZED LEVELS*	
			SECTION 5307 APPORTIONMENT	*OPER. ASSIST. LIMITATION*
OVER 1,000,000 IN POPULATION	$1,452,258,134	$239,805,353	*$2,749,230,539*	*$735,611,460*
200,000-1,000,000 IN POPULATION	333,567,556	67,159,053	*631,467,692*	*206,012,790*
50,000-200,000 IN POPULATION	190,336,313	93,035,594	*360,320,519*	*199,365,974*
NATIONAL TOTAL	$1,976,162,003	$400,000,000	*$3,741,018,750*	*$1,140,990,224*

URBANIZED AREA/STATE	FY 1997 SECTION 5307 APPORTIONMENT	FY 1997 OPERATING ASSISTANCE LIMITATION	*ISTEA FY 1997 AUTHORIZED LEVELS*	
			SECTION 5307 APPORTIONMENT	*OPER. ASSIST. LIMITATION*
Amounts Apportioned and Authorized to Urbanized Areas Over 1,000,000 in Population:				
Atlanta, GA	$28,477,842	$2,816,782	*$53,910,632*	*$8,640,580*
Baltimore, MD	23,961,535	4,508,488	*45,360,931*	*13,829,948*
Boston, MA	54,141,795	8,464,663	*102,494,367*	*25,965,654*
Chicago, IL-Northwestern IN	131,887,681	23,451,339	*249,672,997*	*71,937,818*
Cincinnati, OH-KY	9,632,894	2,442,132	*18,235,770*	*7,491,326*
Cleveland, OH	16,578,429	4,468,291	*31,384,177*	*13,706,642*
Dallas-Fort Worth, TX	25,467,278	4,006,917	*48,211,413*	*12,291,360*
Denver, CO	16,632,395	2,735,492	*31,486,338*	*8,391,219*
Detroit, MI	24,439,855	9,919,871	*46,266,426*	*30,429,558*
Ft Lauderdale-Hollywood-Pompano Bch, FL.	14,766,384	3,402,165	*27,953,841*	*10,436,263*
Houston, TX	30,163,976	4,210,427	*57,102,606*	*12,915,635*
Kansas City, MO-KS	6,785,583	2,069,272	*12,845,602*	*6,347,566*
Los Angeles, CA	130,749,338	26,458,161	*247,518,031*	*81,161,350*
Miami-Hialeah, FL	26,124,578	3,886,369	*49,455,730*	*11,921,576*
Milwaukee, WI	12,085,049	2,532,155	*22,877,878*	*7,767,476*
Minneapolis-St. Paul, MN	17,489,509	3,376,246	*33,108,915*	*10,356,756*
New Orleans, LA	10,940,543	3,062,741	*20,711,245*	*9,395,067*
New York, NY-Northeastern NJ	424,978,676	61,275,249	*804,515,638*	*187,964,005*
Norfolk-Virginia Beach-Newport News, VA	8,671,332	1,945,468	*16,415,463*	*5,967,792*
Philadelphia, PA-NJ	75,007,190	14,750,581	*141,994,079*	*45,247,934*
Phoenix, AZ	15,328,662	2,181,446	*29,018,274*	*6,691,663*
Pittsburgh, PA	21,030,760	4,403,029	*39,812,762*	*13,506,447*
Portland-Vancouver, OR-WA	15,378,663	2,040,154	*29,112,929*	*6,258,245*
Riverside-San Bernardino, CA	11,829,917	1,166,057	*22,394,893*	*3,576,921*
Sacramento, CA	8,986,639	1,612,646	*17,012,362*	*4,946,850*
San Antonio, TX	14,754,224	2,121,955	*27,930,822*	*6,509,173*
San Diego, CA	24,990,971	3,385,852	*47,309,729*	*10,386,223*
San Francisco-Oakland, CA	77,176,216	9,015,230	*146,100,203*	*27,654,539*
San Jose, CA	20,058,868	3,062,957	*37,972,897*	*9,395,728*
San Juan, PR	23,403,297	3,481,285	*44,304,148*	*10,678,964*
Seattle, WA	34,631,213	2,860,757	*65,559,412*	*8,775,474*
St. Louis, MO-IL	16,873,006	4,444,963	*31,941,830*	*13,635,083*
Tampa-St. Petersburg-Clearwater, FL	12,245,969	2,420,122	*23,182,511*	*7,423,810*
Washington, DC-MD-VA	66,587,867	7,826,091	*126,055,688*	*24,006,814*
TOTAL	$1,452,258,134	$239,805,353	*$2,749,230,539*	*$735,611,460*

TABLE 2

FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS AND ISTEA AUTHORIZED LEVELS

URBANIZED AREA/STATE	FY 1997 SECTION 5307 APPORTIONMENT	FY 1997 OPERATING ASSISTANCE LIMITATION	*ISTEA FY 1997 AUTHORIZED LEVELS*	
			SECTION 5307 APPORTIONMENT	*OPER. ASSIST. LIMITATION*
Amounts Apportioned and Authorized to Urbanized Areas 200,000 to 1,000,000 in Population :				
Akron, OH	**$4,059,741**	**$1,067,925**	*$7,685,385*	*$3,275,898*
Albany-Schenectady-Troy, NY	**4,761,264**	**1,035,770**	*9,013,419*	*3,177,262*
Albuquerque, NM	**3,739,626**	**715,783**	*7,079,386*	*2,195,689*
Allentown-Bethlehem-Easton, PA-NJ	**3,194,653**	**1,082,932**	*6,047,711*	*3,321,933*
Anchorage, AK	**1,556,095**	**353,415**	*2,945,800*	*1,084,113*
Ann Arbor, MI	**2,580,614**	**454,078**	*4,885,290*	*1,392,900*
Augusta, GA-SC	**1,323,808**	**361,721**	*2,506,064*	*1,109,591*
Austin, TX	**7,692,115**	**681,184**	*14,561,734*	*2,089,557*
Bakersfield, CA	**2,500,856**	**444,156**	*4,734,303*	*1,362,463*
Baton Rouge, LA	**2,037,036**	**593,526**	*3,856,258*	*1,820,663*
Birmingham, AL	**3,436,853**	**1,090,264**	*6,506,213*	*3,344,425*
Bridgeport-Milford, CT	**4,313,581**	**946,550**	*8,165,923*	*2,903,577*
Buffalo-Niagara Falls, NY	**8,736,460**	**2,778,422**	*16,538,756*	*8,522,905*
Canton, OH	**1,312,653**	**522,973**	*2,484,947*	*1,604,239*
Charleston, SC	**2,091,766**	**495,832**	*3,959,866*	*1,520,981*
Charlotte, NC	**4,242,082**	**597,735**	*8,030,572*	*1,833,572*
Chattanooga, TN-GA	**1,723,265**	**450,609**	*3,262,266*	*1,382,260*
Colorado Springs, CO	**2,682,047**	**447,324**	*5,077,311*	*1,372,181*
Columbia, SC	**1,984,293**	**506,192**	*3,756,412*	*1,552,762*
Columbus, GA-AL	**1,270,244**	**379,273**	*2,404,665*	*1,163,434*
Columbus, OH	**7,728,615**	**2,015,134**	*14,630,832*	*6,181,496*
Corpus Christi, TX	**2,604,032**	**398,027**	*4,929,622*	*1,220,961*
Davenport-Rock Island-Moline, IA-IL	**1,997,317**	**517,895**	*3,781,067*	*1,588,660*
Dayton, OH	**8,324,401**	**1,340,914**	*15,758,697*	*4,113,301*
Daytona Beach, FL	**1,794,688**	**359,635**	*3,397,476*	*1,103,192*
Des Moines, IA	**1,834,582**	**504,401**	*3,472,996*	*1,547,268*
Durham, NC	**2,185,218**	**370,685**	*4,136,777*	*1,137,089*
El Paso, TX-NM	**6,085,157**	**824,995**	*11,519,645*	*2,530,701*
Fayetteville, NC	**1,053,726**	**341,127**	*1,994,781*	*1,046,419*
Flint, MI	**2,730,993**	**701,642**	*5,169,968*	*2,152,313*
Fort Myers-Cape Coral, FL	**1,547,883**	**261,974**	*2,930,256*	*803,615*
Fort Wayne, IN	**1,358,261**	**500,307**	*2,571,288*	*1,534,710*
Fresno, CA	**3,724,661**	**673,282**	*7,051,054*	*2,065,317*
Grand Rapids, MI	**2,856,660**	**711,632**	*5,407,867*	*2,182,957*
Greenville, SC	**1,314,526**	**343,967**	*2,488,493*	*1,055,132*
Harrisburg, PA	**1,569,322**	**519,480**	*2,970,841*	*1,593,523*
Hartford-Middletown, CT	**6,254,556**	**1,054,201**	*11,840,332*	*3,233,801*
Honolulu, HI	**15,442,112**	**1,305,605**	*29,233,045*	*4,004,990*
Indianapolis, IN	**6,189,778**	**1,754,251**	*11,717,700*	*5,381,226*
Jackson, MS	**1,369,139**	**414,700**	*2,591,880*	*1,272,107*
Jacksonville, FL	**5,663,862**	**929,479**	*10,722,103*	*2,851,210*
Knoxville, TN	**1,688,818**	**413,405**	*3,197,055*	*1,268,134*
Lansing-East Lansing, MI	**2,308,274**	**533,655**	*4,369,733*	*1,637,005*
Las Vegas, NV	**7,253,908**	**633,483**	*13,732,175*	*1,943,230*
Lawrence-Haverhill, MA-NH	**2,386,518**	**392,150**	*4,517,853*	*1,202,935*
Lexington-Fayette, KY	**1,385,420**	**594,869**	*2,622,702*	*1,824,783*
Little Rock-North Little Rock, AR	**1,958,848**	**475,665**	*3,708,243*	*1,459,120*

TABLE 2

FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS AND ISTEA AUTHORIZED LEVELS

URBANIZED AREA/STATE	FY 1997 SECTION 5307 APPORTIONMENT	FY 1997 OPERATING ASSISTANCE LIMITATION	*ISTEA FY 1997 AUTHORIZED LEVELS*	
			SECTION 5307 APPORTIONMENT	*OPER. ASSIST. LIMITATION*
Amounts Apportioned and Authorized to Urbanized Areas 200,000 to 1,000,000 in Population (continued):				
Lorain-Elyria, OH	$900,086	$358,820	*$1,703,928*	*$1,100,692*
Louisville, KY-IN	7,160,476	1,791,628	*13,555,303*	*5,495,881*
Madison, WI	3,379,278	457,666	*6,397,219*	*1,403,907*
McAllen-Edinburg-Mission, TX	960,878	380,225	*1,819,012*	*1,166,353*
Melbourne-Palm Bay, FL	1,742,237	323,270	*3,298,180*	*991,643*
Memphis, TN-AR-MS	6,397,414	1,660,461	*12,110,771*	*5,093,522*
Mobile, AL	1,467,031	462,711	*2,777,198*	*1,419,381*
Modesto, CA	2,069,508	455,399	*3,917,730*	*1,396,952*
Montgomery, AL	1,083,840	470,828	*2,051,788*	*1,444,283*
Nashville, TN	3,368,111	769,856	*6,376,080*	*2,361,560*
New Haven-Meriden, CT	6,714,903	1,063,644	*12,711,802*	*3,262,764*
Ogden, UT	2,154,784	321,477	*4,079,163*	*986,142*
Oklahoma City, OK	3,509,969	1,065,517	*6,644,627*	*3,268,511*
Omaha, NE-IA	4,049,887	1,092,759	*7,666,732*	*3,352,078*
Orlando, FL	9,611,472	804,076	*18,195,217*	*2,466,533*
Oxnard-Ventura, CA	4,501,099	623,592	*8,520,908*	*1,912,892*
Pensacola, FL	1,350,328	348,493	*2,556,270*	*1,069,016*
Peoria, IL	1,329,266	485,558	*2,516,396*	*1,489,467*
Providence-Pawtucket, RI-MA	11,115,901	2,182,805	*21,043,209*	*6,695,832*
Provo-Orem, UT	1,937,793	374,224	*3,668,384*	*1,147,944*
Raleigh, NC	2,093,495	335,808	*3,963,139*	*1,030,104*
Reno, NV	2,657,820	387,125	*5,031,446*	*1,187,519*
Richmond, VA	4,238,572	889,458	*8,023,925*	*2,728,444*
Rochester, NY	5,048,775	1,425,823	*9,557,699*	*4,373,764*
Rockford, IL	1,374,700	446,830	*2,602,409*	*1,370,666*
Salt Lake City, UT	9,295,760	1,127,716	*17,597,551*	*3,459,310*
Sarasota-Bradenton, FL	2,758,095	582,139	*5,221,275*	*1,785,732*
Scranton-Wilkes-Barre, PA	2,217,042	800,013	*4,197,022*	*2,454,070*
Shreveport, LA	1,921,434	484,850	*3,637,413*	*1,487,294*
South Bend-Mishawaka, IN-MI	1,630,178	529,654	*3,086,045*	*1,624,733*
Spokane, WA	4,214,409	513,954	*7,978,182*	*1,576,573*
Springfield, MA-CT	4,352,194	933,765	*8,239,020*	*2,864,356*
Stockton, CA	2,331,172	616,566	*4,413,078*	*1,891,339*
Syracuse, NY	3,676,358	875,413	*6,959,614*	*2,685,362*
Tacoma, WA	7,853,575	715,557	*14,867,389*	*2,194,997*
Toledo, OH-MI	3,884,026	1,033,816	*7,352,746*	*3,171,268*
Trenton, NJ-PA	3,619,207	912,780	*6,851,423*	*2,799,985*
Tucson, AZ	5,844,721	764,772	*11,064,483*	*2,345,964*
Tulsa, OK	3,199,661	724,097	*6,057,191*	*2,221,194*
West Palm Bch-Boca Raton-Delray Bch, FL	9,222,658	762,122	*17,459,162*	*2,337,838*
Wichita, KS	2,262,247	626,429	*4,282,599*	*1,921,594*
Wilmington, DE-NJ-MD-PA	4,403,353	926,484	*8,335,866*	*2,842,023*
Worcester, MA-CT	3,064,276	534,786	*5,800,897*	*1,640,475*
Youngstown-Warren, OH	1,749,240	823,863	*3,311,439*	*2,527,228*
TOTAL	$333,567,556	$67,159,053	*$631,467,692*	*$206,012,790*

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FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS AND ISTEA AUTHORIZED LEVELS

URBANIZED AREA/STATE	FY 1997 SECTION 5307 APPORTIONMENT	FY 1997 OPERATING ASSISTANCE LIMITATION	*ISTEA FY 1997 AUTHORIZED LEVELS*	
			SECTION 5307 APPORTIONMENT	*OPER. ASSIST. LIMITATION*
Amounts Apportioned and Authorized to State Governors for Urbanized Areas 50,000 to 200,000 in Population:				
ALABAMA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$3,564,706**	**$1,970,561**	*$6,748,248*	*$4,221,424*
Anniston, AL	**343,841**	**231,980**	*650,915*	*496,959*
Auburn-Opelika, AL	**275,863**	**129,622**	*522,229*	*277,681*
Decatur, AL	**314,845**	**152,422**	*596,024*	*326,525*
Dothan, AL	**264,445**	**133,304**	*500,614*	*285,569*
Florence, AL	**368,413**	**235,002**	*697,433*	*503,431*
Gadsden, AL	**325,615**	**233,057**	*616,413*	*499,266*
Huntsville	**1,033,647**	**504,984**	*1,956,769*	*1,081,800*
Tuscaloosa, AL	**638,037**	**350,190**	*1,207,851*	*750,193*
ALASKA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$0**	**$0**	*$0*	*$0*
ARIZONA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$933,084**	**$292,757**	*$1,766,394*	*$688,089*
Flagstaff, AZ	**367,077**	**85,791**	*694,903*	*244,718*
Yuma, AZ-CA (AZ)	**566,007**	**206,966**	*1,071,491*	*443,371*
ARKANSAS:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$1,361,973**	**$798,674**	*$2,578,316*	*$1,710,956*
Fayetteville-Springdale, AR	**375,881**	**168,344**	*711,570*	*360,634*
Fort Smith, AR-OK (AR)	**511,676**	**275,251**	*968,641*	*589,656*
Pine Bluff, AR	**345,780**	**269,436**	*654,587*	*577,198*
Texarkana, TX-AR (AR)	**128,636**	**85,643**	*243,518*	*183,467*
CALIFORNIA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$20,862,343**	**$6,801,253**	*$39,493,935*	*$14,569,951*
Antioch-Pittsburg, CA	**1,179,816**	**345,636**	*2,233,477*	*740,438*
Chico, CA	**515,132**	**185,098**	*975,182*	*396,526*
Davis, CA	**625,337**	**213,010**	*1,183,809*	*456,320*
Fairfield, CA	**759,495**	**255,671**	*1,437,779*	*547,710*
Hemet-San Jacinto, CA	**633,643**	**195,698**	*1,199,533*	*419,232*
Hesperia-Apple Valley-Victorville, CA	**808,344**	**265,938**	*1,530,254*	*569,705*
Indio-Coachella, CA	**383,147**	**126,070**	*725,325*	*270,072*
Lancaster-Palmdale, CA	**1,359,656**	**162,437**	*2,573,928*	*347,980*
Lodi, CA	**532,299**	**175,169**	*1,007,680*	*375,256*

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FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS AND ISTEA AUTHORIZED LEVELS

URBANIZED AREA/STATE	FY 1997 SECTION 5307 APPORTIONMENT	FY 1997 OPERATING ASSISTANCE LIMITATION	*ISTEA FY 1997 AUTHORIZED LEVELS*	
			SECTION 5307 APPORTIONMENT	*OPER. ASSIST. LIMITATION*
CALIFORNIA (Continued):				
Lompoc, CA	**326,914**	**107,558**	*618,871*	*230,415*
Merced, CA	**581,189**	**188,067**	*1,100,233*	*402,886*
Napa, CA	**607,279**	**266,728**	*1,149,624*	*571,396*
Palm Springs, CA	**756,568**	**180,689**	*1,432,238*	*387,080*
Redding, CA	**437,460**	**149,645**	*828,144*	*320,576*
Salinas, CA	**1,151,186**	**423,192**	*2,179,280*	*906,580*
San Luis Obispo, CA	**545,161**	**179,409**	*1,032,030*	*384,338*
Santa Barbara, CA	**1,780,940**	**700,123**	*3,371,449*	*1,499,836*
Santa Cruz, CA	**920,903**	**376,707**	*1,743,337*	*806,999*
Santa Maria, CA	**837,847**	**227,014**	*1,586,105*	*486,319*
Santa Rosa, CA	**1,624,493**	**449,066**	*3,075,283*	*962,010*
Seaside-Monterey, CA	**1,091,625**	**521,884**	*2,066,527*	*1,118,004*
Simi Valley, CA	**1,033,302**	**306,429**	*1,956,115*	*656,445*
Vacaville, CA	**627,290**	**206,423**	*1,187,506*	*442,209*
Visalia	**716,502**	**225,542**	*1,356,391*	*483,166*
Watsonville, CA	**394,734**	**129,889**	*747,259*	*278,253*
Yuba City, CA	**629,839**	**236,597**	*1,192,331*	*506,849*
Yuma, AZ-CA (CA)	**2,242**	**1,564**	*4,245*	*3,351*
COLORADO:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$3,844,091**	**$1,839,230**	*$7,277,145*	*$3,940,083*
Boulder, CO	**855,368**	**412,508**	*1,619,274*	*883,694*
Fort Collins, C0	**712,440**	**294,588**	*1,348,701*	*631,080*
Grand Junction, CO	**405,635**	**189,506**	*767,897*	*405,969*
Greeley, CO	**569,821**	**283,630**	*1,078,713*	*607,605*
Longmont, CO	**519,272**	**170,885**	*983,019*	*366,077*
Pueblo, CO	**781,555**	**488,113**	*1,479,541*	*1,045,659*
CONNECTICUT:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$12,953,976**	**$4,543,229**	*$24,522,821*	*$9,732,709*
Bristol, CT	**605,888**	**297,793**	*1,146,989*	*637,945*
Danbury, CT-NY (CT)	**2,196,021**	**492,302**	*4,157,228*	*1,054,632*
New Britain, CT	**1,134,519**	**626,111**	*2,147,727*	*1,341,282*
New London-Norwich, CT	**912,955**	**533,937**	*1,728,291*	*1,143,824*
Norwalk, CT	**2,322,457**	**676,464**	*4,396,581*	*1,449,151*
Stamford, CT-NY (CT)	**2,931,943**	**1,016,038**	*5,550,382*	*2,176,602*
Waterbury, CT	**2,850,193**	**900,584**	*5,395,623*	*1,929,273*

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FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS AND ISTEA AUTHORIZED LEVELS

URBANIZED AREA/STATE	FY 1997 SECTION 5307 APPORTIONMENT	FY 1997 OPERATING ASSISTANCE LIMITATION	*ISTEA FY 1997 AUTHORIZED LEVELS*	
			SECTION 5307 APPORTIONMENT	*OPER. ASSIST. LIMITATION*
DELAWARE:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$290,008**	**$95,414**	*$549,007*	*$204,401*
Dover, DE	**290,008**	**95,414**	*549,007*	*204,401*
FLORIDA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$8,838,818**	**$3,152,975**	*$16,732,526*	*$6,754,444*
Deltona, FL	**293,887**	**96,684**	*556,350*	*207,121*
Fort Pierce, F	**704,001**	**205,216**	*1,332,725*	*439,623*
Fort Walton Beach, FL	**682,437**	**258,405**	*1,291,902*	*553,566*
Gainesville, FL	**874,586**	**351,847**	*1,655,655*	*753,742*
Kissimmee, FL	**407,355**	**134,039**	*771,153*	*287,145*
Lakeland, FL	**894,093**	**345,542**	*1,692,584*	*740,235*
Naples, FL	**588,435**	**146,868**	*1,113,950*	*314,628*
Ocala, FL	**395,279**	**147,105**	*748,292*	*315,135*
Panama City, FL	**593,205**	**234,999**	*1,122,981*	*503,426*
Punta Gorda, FL	**387,921**	**127,629**	*734,362*	*273,413*
Spring Hill, FL	**296,545**	**97,565**	*561,381*	*209,008*
Stuart, FL	**517,420**	**170,246**	*979,514*	*364,708*
Tallahassee, FL	**996,984**	**393,861**	*1,887,364*	*843,747*
Titusville, FL.	**285,395**	**93,895**	*540,273*	*201,146*
Vero Beach, FL	**361,442**	**118,916**	*684,236*	*254,746*
Winter Haven, FL.	**559,833**	**230,158**	*1,059,804*	*493,054*
GEORGIA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$3,869,856**	**$2,169,758**	*$7,325,925*	*$4,648,153*
Albany, GA.	**479,330**	**316,131**	*907,408*	*677,230*
Athens, GA.	**459,567**	**197,454**	*869,995*	*422,995*
Brunswick, GA	**264,466**	**87,007**	*500,653*	*186,390*
Macon, GA.	**859,125**	**542,798**	*1,626,387*	*1,162,807*
Rome, GA.	**269,608**	**149,674**	*510,388*	*320,639*
Savannah, GA	**1,124,074**	**689,903**	*2,127,955*	*1,477,940*
Warner Robins, GA	**413,686**	**186,791**	*783,139*	*400,153*
HAWAII:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$1,028,506**	**$475,852**	*$1,947,037*	*$1,019,392*
Kailua, HI	**1,028,506**	**475,852**	*1,947,037*	*1,019,392*

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FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS AND ISTEA AUTHORIZED LEVELS

URBANIZED AREA/STATE	FY 1997 SECTION 5307 APPORTIONMENT	FY 1997 OPERATING ASSISTANCE LIMITATION	*ISTEA FY 1997 AUTHORIZED LEVELS*	
			SECTION 5307 APPORTIONMENT	*OPER. ASSIST. LIMITATION*
IDAHO:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$2,035,598**	**$809,759**	*$3,853,535*	*1,734,702*
Boise City, ID	**1,245,611**	**469,898**	*2,358,032*	*1,006,635*
Idaho Falls, ID	**446,527**	**146,933**	*845,309*	*314,767*
Pocatello, ID	**343,460**	**192,928**	*650,194*	*413,299*
ILLINOIS:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$9,324,061**	**$5,371,412**	*$17,651,130*	*11,506,880*
Alton, IL	**503,900**	**372,784**	*953,920*	*798,596*
Aurora, IL	**1,411,277**	**723,464**	*2,671,651*	*1,549,835*
Beloit, WI-IL (IL)	**64,402**	**25,498**	*121,919*	*54,622*
Bloomington-Normal, IL	**811,785**	**382,645**	*1,536,768*	*819,719*
Champaign-Urbana, IL	**1,145,586**	**616,763**	*2,168,678*	*1,321,258*
Crystal Lake, IL	**459,966**	**151,340**	*870,749*	*324,208*
Decatur, IL	**644,855**	**446,782**	*1,220,757*	*957,116*
Dubuque, IA-IL (IL)	**15,021**	**8,765**	*28,436*	*18,777*
Elgin, IL	**1,018,027**	**636,793**	*1,927,198*	*1,364,167*
Joliet, IL	**1,177,134**	**953,579**	*2,228,401*	*2,042,801*
Kankakee, IL.	**461,991**	**262,596**	*874,583*	*562,545*
Round Lake Beach-McHenry, IL-WI (IL)	**670,393**	**209,575**	*1,269,103*	*448,962*
Springfield, IL.	**939,724**	**580,828**	*1,778,967*	*1,244,275*
INDIANA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$5,438,198**	**$3,063,742**	*$10,294,905*	*$6,563,286*
Anderson, IN	**439,561**	**303,284**	*832,121*	*649,710*
Bloomington, IN	**655,933**	**287,968**	*1,241,729*	*616,897*
Elkhart-GosheN, IN	**657,411**	**288,505**	*1,244,528*	*618,047*
Evansville, IN-KY (IN)	**1,217,849**	**712,185**	*2,305,478*	*1,525,675*
Kokomo, IN	**442,654**	**265,091**	*837,976*	*567,891*
Lafayette-West Lafayette, IN	**880,021**	**439,016**	*1,665,944*	*940,481*
Muncie, IN	**646,927**	**435,588**	*1,224,679*	*933,136*
Terre Haute, IN	**497,842**	**332,105**	*942,450*	*711,449*
IOWA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$2,960,493**	**$1,777,815**	*$5,604,427*	*$3,808,516*
Cedar Rapids, IA	**920,022**	**542,576**	*1,741,668*	*1,162,331*
Dubuque, IA-IL (IA)	**447,809**	**302,695**	*847,736*	*648,447*
Iowa City, IA	**530,093**	**207,305**	*1,003,505*	*444,099*
Sioux City, IA-NE-SD (IA)	**489,595**	**311,588**	*926,837*	*667,498*
Waterloo-Cedar Falls, IA	**572,974**	**413,651**	*1,084,681*	*886,141*

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URBANIZED AREA/STATE	FY 1997 SECTION 5307 APPORTIONMENT	FY 1997 OPERATING ASSISTANCE LIMITATION	*ISTEA FY 1997 AUTHORIZED LEVELS*	
			SECTION 5307 APPORTIONMENT	*OPER. ASSIST. LIMITATION*
KANSAS:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$1,437,410**	**$759,970**	*$2,721,124*	*$1,628,042*
Lawrence, KS	**544,317**	**217,653**	*1,030,433*	*466,267*
St. Joseph, MO-KS (KS)	**4,493**	**3,866**	*8,506*	*8,283*
Topeka, KS	**888,600**	**538,451**	*1,682,185*	*1,153,493*
KENTUCKY:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$1,132,915**	**$635,567**	*$2,144,690*	*$1,361,539*
Clarksville, TN-KY (KY)	**138,239**	**73,054**	*261,697*	*156,501*
Evansville, IN-KY (KY)	**169,754**	**45,056**	*321,356*	*96,520*
Huntington-Ashland, WV-KY-OH ((KY)	**338,518**	**218,446**	*640,839*	*467,964*
Owensboro, KY	**486,404**	**299,011**	*920,798*	*640,555*
LOUISIANA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$3,355,232**	**$1,868,922**	*$6,351,700*	*$4,003,690*
Alexandria, LA	**489,624**	**326,140**	*926,894*	*698,673*
Houma, LA	**344,401**	**192,233**	*651,976*	*411,811*
Lafayette, LA	**847,168**	**428,989**	*1,603,751*	*919,000*
Lake Charles, LA	**680,516**	**413,989**	*1,288,266*	*886,866*
Monroe, LA	**647,066**	**393,577**	*1,224,944*	*843,138*
Slidell, LA	**346,457**	**113,994**	*655,869*	*244,202*
MAINE:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$1,460,258**	**$808,464**	*$2,764,375*	*$1,731,928*
Bangor, ME	**300,059**	**152,758**	*568,033*	*327,246*
Lewiston-Auburn, ME	**348,663**	**215,633**	*660,045*	*461,938*
Portland, ME	**745,522**	**409,648**	*1,411,328*	*877,566*
Portsmouth-Dover-Rochester, NH-ME (ME)	**66,014**	**30,425**	*124,969*	*65,178*
MARYLAND:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$1,623,878**	**$751,514**	*$3,074,118*	*$1,609,927*
Annapolis, MD	**528,899**	**228,635**	*1,001,245*	*489,792*
Cumberland, MD-WV (MD)	**281,298**	**180,307**	*532,517*	*386,263*
Frederick, MD	**381,627**	**125,567**	*722,447*	*268,995*
Hagerstown, MD-PA-WV (MD)	**432,054**	**217,005**	*817,909*	*464,878*

TABLE 2

FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS AND ISTEA AUTHORIZED LEVELS

URBANIZED AREA/STATE	FY 1997 SECTION 5307 APPORTIONMENT	FY 1997 OPERATING ASSISTANCE LIMITATION	*ISTEA FY 1997 AUTHORIZED LEVELS*	
			SECTION 5307 APPORTIONMENT	*OPER. ASSIST. LIMITATION*
MASSACHUSETTS:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$6,431,297**	**$4,010,979**	*$12,174,914*	*$8,592,499*
Brockton, MA	**1,174,807**	**966,707**	*2,223,995*	*2,070,923*
Fall River, MA-RI (MA)	**1,145,818**	**628,972**	*2,169,118*	*1,347,412*
Fitchburg-Leominster, MA	**464,336**	**265,581**	*879,023*	*568,940*
Hyannis, MA	**331,586**	**109,085**	*627,716*	*233,687*
Lowell, MA-NH (MA)	**1,454,227**	**997,173**	*2,752,957*	*2,136,189*
New Bedford, MA	**1,260,158**	**695,995**	*2,385,571*	*1,490,992*
Pittsfield, MA	**300,162**	**211,988**	*568,229*	*454,130*
Taunton, MA	**300,203**	**135,478**	*568,305*	*290,227*
MICHIGAN:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$5,488,211**	**$3,283,763**	*$10,389,586*	*$7,034,625*
Battle Creek, MI	**458,369**	**313,820**	*867,726*	*672,278*
Bay City, MI	**512,072**	**343,896**	*969,390*	*736,709*
Benton Harbor, MI	**370,395**	**211,224**	*701,185*	*452,494*
Holland, MI	**415,701**	**136,779**	*786,952*	*293,015*
Jackson, MI	**511,790**	**327,621**	*968,857*	*701,844*
Kalamazoo, MI	**1,105,188**	**614,106**	*2,092,202*	*1,315,565*
Muskegon, MI	**674,119**	**414,697**	*1,276,157*	*888,384*
Port Huron, MI	**443,651**	**218,257**	*839,864*	*467,559*
Saginaw, MI	**996,926**	**703,363**	*1,887,253*	*1,506,776*
MINNESOTA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$1,955,838**	**$1,090,931**	*$3,702,543*	*$2,337,042*
Duluth, MN-WI (MN)	**475,940**	**358,439**	*900,990*	*767,864*
Fargo-Moorhead, ND-MN (MN)	**275,192**	**152,304**	*520,958*	*326,273*
Grand Forks, ND-MN (MN)	**60,313**	**37,533**	*114,176*	*80,406*
La Crosse, WI-MN (MN)	**29,545**	**12,455**	*55,931*	*26,681*
Rochester, MN	**536,812**	**287,183**	*1,016,224*	*615,217*
St. Cloud, MN	**578,036**	**243,017**	*1,094,264*	*520,601*
MISSISSIPPI:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$1,679,127**	**$906,680**	*$3,178,708*	*$1,942,330*
Biloxi-Gulfport, MS	**1,039,596**	**552,169**	*1,968,030*	*1,182,881*
Hattiesburg, MS	**324,011**	**166,061**	*613,377*	*355,743*
Pascagoula, MS	**315,520**	**188,450**	*597,301*	*403,706*

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FEDERAL TRANSIT ADMINISTRATION

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URBANIZED AREA/STATE	FY 1997 SECTION 5307 APPORTIONMENT	FY 1997 OPERATING ASSISTANCE LIMITATION	*ISTEA FY 1997 AUTHORIZED LEVELS*	
			SECTION 5307 APPORTIONMENT	*OPER. ASSIST. LIMITATION*
MISSOURI:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$2,313,860**	**$1,205,239**	*$4,380,305*	*$2,581,917*
Columbia, MO	**456,815**	**222,473**	*864,784*	*476,592*
Joplin, MO	**320,811**	**158,607**	*607,318*	*339,775*
Springfield, MO	**1,077,678**	**512,465**	*2,040,123*	*1,097,825*
St. Joseph, MO-KS (MO)	**458,556**	**311,694**	*868,080*	*667,725*
MONTANA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$1,540,339**	**$865,821**	*$2,915,974*	*$1,854,801*
Billings, MT	**594,047**	**332,854**	*1,124,574*	*713,056*
Great Falls, MT	**553,960**	**324,442**	*1,048,687*	*695,033*
Missoula, MT	**392,332**	**208,525**	*742,713*	*446,711*
NEBRASKA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$1,712,384**	**$783,608**	*$3,241,669*	*$1,678,680*
Lincoln, NE	**1,638,309**	**747,115**	*3,101,439*	*1,600,503*
Sioux City, IA-NE-SD (NE)	**74,075**	**36,493**	*140,230*	*78,177*
NEVADA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$0**	**$0**	*$0*	*$0*
NEW HAMPSHIRE:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$2,079,451**	**$930,889**	*$3,936,554*	*$1,994,193*
Lowell, MA-NH (NH)	**4,256**	**1,136**	*8,057*	*2,434*
Manchester, NH	**871,739**	**425,529**	*1,650,265*	*911,588*
Nashua, NH	**697,101**	**270,768**	*1,319,664*	*580,051*
Portsmouth-Dover-Rochester, NH-ME (NH)	**506,355**	**233,456**	*958,568*	*500,120*
NEW JERSEY:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$1,575,569**	**$1,162,152**	*$2,982,666*	*$2,489,615*
Atlantic City, NJ	**1,135,623**	**913,408**	*2,149,817*	*1,956,744*
Vineland-Millville, NJ	**439,946**	**248,744**	*832,849*	*532,871*
NEW MEXICO:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$857,983**	**$346,371**	*$1,624,224*	*$742,011*
Las Cruces, NM	**476,613**	**185,079**	*902,263*	*396,484*

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FEDERAL TRANSIT ADMINISTRATION

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URBANIZED AREA/STATE	FY 1997 SECTION 5307 APPORTIONMENT	FY 1997 OPERATING ASSISTANCE LIMITATION	*ISTEA FY 1997 AUTHORIZED LEVELS*	
			SECTION 5307 APPORTIONMENT	*OPER. ASSIST. LIMITATION*
NEW MEXICO (Continued):				
Santa Fe, NM	**381,370**	**$161,292**	*721,961*	*345,526*
NEW YORK:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$4,760,359**	**$2,887,397**	*$9,011,707*	*$6,185,513*
Binghamton, NY	**1,194,868**	**753,963**	*2,261,973*	*1,615,174*
Danbury, CT-NY (NY)	**16,195**	**4,225**	*30,659*	*9,051*
Elmira, NY	**490,651**	**328,474**	*928,838*	*703,671*
Glens Falls, NY	**337,413**	**163,510**	*638,747*	*350,280*
Ithaca, NY	**340,544**	**112,051**	*644,674*	*240,041*
Newburgh, NY	**442,206**	**203,473**	*837,129*	*435,889*
Poughkeepsie, NY	**928,913**	**630,599**	*1,758,500*	*1,350,899*
Stamford, CT-NY (NY)	**110**	**109**	*208*	*233*
Utica-Rome, NY	**1,009,459**	**690,993**	*1,910,979*	*1,480,275*
NORTH CAROLINA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$7,727,991**	**$3,807,386**	*$14,629,652*	*$8,156,353*
Asheville, NC	**596,503**	**313,739**	*1,129,223*	*672,106*
Burlington, NC	**432,712**	**238,562**	*819,155*	*511,059*
Gastonia, NC	**633,594**	**363,032**	*1,199,439*	*777,704*
Goldsboro, NC	**329,040**	**162,993**	*622,898*	*349,171*
Greensboro, NC	**1,362,734**	**686,529**	*2,579,756*	*1,470,716*
Greenville, NC	**378,854**	**124,657**	*717,199*	*267,045*
Hickory, NC	**361,323**	**173,702**	*684,011*	*372,112*
High Point, NC	**609,324**	**357,277**	*1,153,496*	*765,375*
Jacksonville, NC	**588,279**	**205,012**	*1,113,655*	*439,187*
Kannapolis, NC	**424,687**	**207,368**	*803,963*	*444,232*
Rocky Mount, NC	**339,486**	**111,702**	*642,671*	*239,293*
Wilmington, NC	**555,275**	**259,914**	*1,051,176*	*556,799*
Winston-Salem, NC	**1,116,180**	**602,897**	*2,113,010*	*1,291,554*
NORTH DAKOTA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$1,501,536**	**$694,941**	*$2,842,518*	*$1,488,734*
Bismarck, ND	**432,980**	**217,303**	*819,662*	*465,516*
Fargo-Moorhead, ND-MN (ND)	**626,200**	**285,401**	*1,185,442*	*611,399*
Grand Forks, ND-MN (ND)	**442,356**	**192,237**	*837,414*	*411,819*
OHIO:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$4,128,528**	**$2,454,959**	*$7,815,605*	*$5,259,124*
Hamilton, OH	**853,330**	**413,830**	*1,615,417*	*886,526*
Huntington-Ashland, WV-KY-OH (OH)	**217,304**	**123,238**	*411,371*	*264,005*
Lima, OH	**466,372**	**296,760**	*882,877*	*635,732*

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FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS AND ISTEA AUTHORIZED LEVELS

URBANIZED AREA/STATE	FY 1997 SECTION 5307 APPORTIONMENT	FY 1997 OPERATING ASSISTANCE LIMITATION	*ISTEA FY 1997 AUTHORIZED LEVELS*	
			SECTION 5307 APPORTIONMENT	*OPER. ASSIST. LIMITATION*
OHIO (Continued):				
Mansfield, OH	**450,264**	**$297,105**	*852,383*	*636,471*
Middletown, OH	**586,711**	**286,086**	*1,110,686*	*612,866*
Newark, OH	**357,476**	**171,899**	*676,728*	*368,249*
Parkersburg, WV-OH (OH)	**52,934**	**31,162**	*100,208*	*66,758*
Sharon, PA-OH (OH)	**34,906**	**20,995**	*66,080*	*44,977*
Springfield, OH	**678,666**	**453,628**	*1,284,764*	*971,781*
Steubenville-Weirton, OH-WV-PA (OH)	**244,159**	**194,158**	*462,211*	*415,934*
Wheeling, WV-OH (OH)	**186,406**	**166,098**	*352,880*	*355,824*
OKLAHOMA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$642,583**	**$386,416**	*$1,216,456*	*$827,798*
Fort Smith, AR-OK (OK)	**11,273**	**6,655**	*21,340*	*14,256*
Lawton, OK	**631,310**	**379,761**	*1,195,116*	*813,541*
OREGON:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$3,351,054**	**$1,425,107**	*$6,343,789*	*$3,052,929*
Eugene-Springfield, OR	**1,577,414**	**725,646**	*2,986,160*	*1,554,510*
Longview, WA-OR (OR)	**10,491**	**5,369**	*19,859*	*11,502*
Medford, OR	**487,494**	**194,556**	*922,862*	*416,787*
Salem, OR	**1,275,655**	**499,536**	*2,414,908*	*1,070,129*
PENNSYLVANIA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$8,760,250**	**$5,129,718**	*$16,583,791*	*$10,989,113*
Altoona, PA	**598,447**	**408,051**	*1,132,903*	*874,145*
Erie, PA	**1,539,491**	**929,251**	*2,914,369*	*1,990,684*
Hagerstown, MD-PA-WV (PA)	**5,274**	**3,855**	*9,984*	*8,259*
Johnstown, PA	**551,862**	**437,207**	*1,044,714*	*936,604*
Lancaster, PA	**1,391,900**	**607,678**	*2,634,967*	*1,301,795*
Monessen, PA	**378,791**	**211,581**	*717,079*	*453,259*
Pottstown, PA	**359,452**	**118,272**	*680,469*	*253,368*
Reading, PA	**1,624,799**	**1,108,504**	*3,075,864*	*2,374,684*
Sharon, PA-OH (PA)	**251,650**	**184,335**	*476,392*	*394,891*
State College, PA	**523,744**	**250,976**	*991,486*	*537,653*
Steubenville-Weirton, OH-WV-PA (PA)	**1,829**	**681**	*3,463*	*1,460*
Williamsport, PA	**439,038**	**277,812**	*831,131*	*595,142*
York, PA	**1,093,973**	**591,515**	*2,070,970*	*1,267,169*
PUERTO RICO:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$8,092,619**	**$3,312,130**	*$15,319,911*	*$7,095,395*
Aguadilla, PR	**707,995**	**245,837**	*1,340,287*	*526,644*
Arecibo, PR	**661,533**	**284,696**	*1,252,330*	*609,889*

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URBANIZED AREA/STATE	FY 1997 SECTION 5307 APPORTIONMENT	FY 1997 OPERATING ASSISTANCE LIMITATION	*ISTEA FY 1997 AUTHORIZED LEVELS*	
			SECTION 5307 APPORTIONMENT	*OPER. ASSIST. LIMITATION*
PUERTO RICO (Continued):				
Caguas, PR	**1,732,461**	**$615,765**	*3,279,675*	*1,319,119*
Cayey, PR	**512,224**	**168,563**	*969,678*	*361,103*
Humacao, PR	**443,320**	**145,877**	*839,237*	*312,504*
Mayaguez, PR	**952,473**	**453,778**	*1,803,101*	*972,104*
Ponce, PR	**2,119,540**	**1,056,142**	*4,012,435*	*2,262,514*
Vega Baja-Manati, PR	**963,073**	**341,472**	*1,823,168*	*731,517*
RHODE ISLAND:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$515,118**	**$246,288**	*$975,155*	*$527,609*
Fall River, MA-RI (RI)	**118,087**	**54,179**	*223,547*	*116,065*
Newport, RI	**397,031**	**192,109**	*751,608*	*411,544*
SOUTH CAROLINA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$2,181,467**	**$1,013,149**	*$4,129,679*	*$2,170,414*
Anderson, SC	**293,390**	**158,795**	*555,409*	*340,178*
Florence, SC	**301,774**	**166,525**	*571,281*	*356,736*
Myrtle Beach, SC	**316,467**	**104,116**	*599,095*	*223,043*
Rock Hill, SC	**336,020**	**149,201**	*636,111*	*319,625*
Spartanburg, SC	**585,757**	**319,995**	*1,108,881*	*685,507*
Sumter, SC	**348,059**	**114,517**	*658,902*	*245,324*
SOUTH DAKOTA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$1,083,163**	**$523,345**	*$2,050,506*	*$1,121,134*
Rapid City, SD	**344,971**	**177,805**	*653,055*	*380,901*
Sioux City, IA-NE-SD (SD)	**9,672**	**4,219**	*18,310*	*9,038*
Sioux Falls, SD	**728,520**	**341,321**	*1,379,141*	*731,195*
TENNESSEE:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$1,676,389**	**$887,865**	*$3,173,527*	*$1,902,024*
Bristol, TN-Bristol, VA (TN)	**156,692**	**90,241**	*296,630*	*193,317*
Clarksville, TN-KY (TN)	**382,042**	**167,264**	*723,232*	*358,320*
Jackson, TN	**289,169**	**148,661**	*547,419*	*318,468*
Johnson City, TN	**440,788**	**228,788**	*834,444*	*490,121*
Kingsport, TN-VA (TN)	**407,698**	**252,911**	*771,802*	*541,797*
TEXAS:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$15,521,819**	**$7,687,065**	*$29,383,932*	*$16,467,577*
Abilene, TX	**550,689**	**322,174**	*1,042,495*	*690,176*
Amarillo, TX	**1,021,405**	**544,163**	*1,933,594*	*1,165,730*

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			SECTION 5307 APPORTIONMENT	*OPER. ASSIST. LIMITATION*
TEXAS (Continued):				
Beaumont, TX	**702,504**	**$436,937**	*1,329,892*	*936,026*
Brownsville, TX	**1,021,066**	**343,413**	*1,932,952*	*735,675*
Bryan-College Station, TX	**683,950**	**248,808**	*1,294,766*	*533,007*
Denton, TX	**369,451**	**121,550**	*699,397*	*260,390*
Galveston, TX	**391,903**	**263,556**	*741,901*	*564,601*
Harlingen, TX	**501,826**	**213,740**	*949,994*	*457,884*
Killeen, TX	**959,855**	**322,616**	*1,817,076*	*691,123*
Laredo, TX	**1,212,263**	**440,079**	*2,294,902*	*942,756*
Lewisville, TX	**426,499**	**140,316**	*807,394*	*300,591*
Longview, TX	**419,622**	**205,890**	*794,374*	*441,067*
Lubbock, TX	**1,195,059**	**634,745**	*2,262,334*	*1,359,780*
Midland, TX	**523,615**	**258,553**	*991,242*	*553,883*
Odessa, TX	**580,880**	**408,081**	*1,099,647*	*874,210*
Port Arthur, TX	**633,651**	**418,221**	*1,199,548*	*895,932*
San Angelo, TX	**544,495**	**269,195**	*1,030,769*	*576,682*
Sherman-Denison, TX	**272,555**	**197,337**	*515,966*	*422,744*
Temple, TX	**309,425**	**147,551**	*585,765*	*316,090*
Texarkana, TX-AR (TX)	**249,682**	**142,859**	*472,665*	*306,038*
Texas City, TX	**663,701**	**308,822**	*1,256,435*	*661,573*
Tyler, TX	**518,996**	**272,311**	*982,496*	*583,357*
Victoria, TX	**359,779**	**202,360**	*681,088*	*433,504*
Waco, TX	**783,791**	**436,203**	*1,483,773*	*934,453*
Wichita Falls, TX	**625,157**	**387,585**	*1,183,467*	*830,302*
UTAH:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$310,232**	**$102,073**	*$587,292*	*$218,665*
Logan, UT	**310,232**	**102,073**	*587,292*	*218,665*
VERMONT:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$544,366**	**$244,385**	*$1,030,525*	*$523,533*
Burlington, VT	**544,366**	**244,385**	*1,030,525*	*523,533*
VIRGINIA:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$3,613,475**	**$2,010,460**	*$6,840,569*	*$4,306,898*
Bristol, TN-Bristol, VA (VA)	**111,554**	**54,597**	*211,179*	*116,960*
Charlottesville, VA	**519,581**	**258,207**	*983,604*	*553,142*
Danville, VA	**295,060**	**182,428**	*558,569*	*390,805*
Fredericksburg, VA	**346,408**	**113,974**	*655,775*	*244,161*
Kingsport, TN-VA (VA)	**21,061**	**15,609**	*39,870*	*33,438*
Lynchburg, VA	**494,304**	**290,441**	*935,753*	*622,196*
Petersburg, VA	**626,641**	**414,079**	*1,186,277*	*887,059*
Roanoke, VA	**1,198,866**	**681,125**	*2,269,542*	*1,459,137*

TABLE 2

FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS AND ISTEA AUTHORIZED LEVELS

URBANIZED AREA/STATE	FY 1997 SECTION 5307 APPORTIONMENT	FY 1997 OPERATING ASSISTANCE LIMITATION	*ISTEA FY 1997 AUTHORIZED LEVELS*	
			SECTION 5307 APPORTIONMENT	*OPER. ASSIST. LIMITATION*
WASHINGTON:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$3,414,794**	**$1,441,915**	*$6,464,458*	*$3,088,935*
Bellingham, WA	**402,330**	**178,042**	*761,640*	*381,410*
Bremerton, WA	**779,388**	**218,876**	*1,475,439*	*468,886*
Longview, WA-OR (WA)	**340,435**	**172,874**	*644,470*	*370,337*
Olympia, WA	**606,370**	**220,296**	*1,147,903*	*471,927*
Richland-Kennewick-Pasco, WA	**632,578**	**328,900**	*1,197,517*	*704,585*
Yakima, WA	**653,693**	**322,927**	*1,237,489*	*691,790*
WEST VIRGINIA				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$2,624,443**	**$1,811,406**	*$4,968,262*	*$3,880,476*
Charleston, WV	**1,055,770**	**668,361**	*1,998,650*	*1,431,794*
Cumberland, MD-WV (WV)	**12,627**	**10,483**	*23,904*	*22,457*
Hagerstown, MD-PA-WV (WV)	**3,189**	**2,443**	*6,037*	*5,233*
Huntington-Ashland, WV-KY-OH (WV)	**592,751**	**434,965**	*1,122,120*	*931,802*
Parkersburg, WV-OH (WV)	**381,215**	**275,348**	*721,667*	*589,863*
Steubenville-Weirton, OH-WV-PA (WV)	**164,015**	**128,467**	*310,493*	*275,207*
Wheeling, WV-OH (WV)	**414,876**	**291,339**	*785,391*	*624,120*
WISCONSIN:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$7,184,516**	**$3,935,089**	*$13,600,811*	*$8,429,924*
Appleton-Neenah, WI	**1,315,612**	**655,709**	*2,490,549*	*1,404,689*
Beloit, WI-IL (WI)	**282,004**	**155,628**	*533,854*	*333,394*
Duluth, MN-WI (WI)	**123,525**	**94,707**	*233,842*	*202,886*
Eau Claire, WI	**515,308**	**237,885**	*975,516*	*509,608*
Green Bay, WI	**999,216**	**506,229**	*1,891,588*	*1,084,466*
Janesville, WI	**379,237**	**194,329**	*717,924*	*416,299*
Kenosha, WI	**690,518**	**483,440**	*1,307,200*	*1,035,646*
La Crosse, WI-MN (WI)	**548,190**	**276,146**	*1,037,763*	*591,573*
Oshkosh, WI	**478,416**	**282,563**	*905,677*	*605,318*
Racine, WI	**1,066,505**	**621,866**	*2,018,971*	*1,332,189*
Round Lake Beach-McHenry, IL-WI (WI)	**400**	**99**	*757*	*211*
Sheboygan, WI	**450,755**	**238,772**	*853,312*	*511,509*
Wausau, WI	**334,830**	**187,716**	*633,858*	*402,134*
WYOMING:				
State apportionment and limitation for areas 50,000 to 200,000 in population:	**$752,148**	**$461,199**	*$1,423,873*	*$988,001*
Casper, WY	**345,029**	**247,399**	*653,166*	*529,989*
Cheyenne, WY	**407,119**	**213,800**	*770,707*	*458,012*
TOTAL	**$190,336,313**	**$93,035,594**	*$360,320,519*	*$199,365,974*

TABLE 3

FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5311 NONURBANIZED AREA FORMULA APPORTIONMENTS, SECTION 5311(b) RURAL TRANSIT ASSISTANCE PROGRAM (RTAP) ALOCATIONS, AND ISTEA AUTHORIZED LEVELS

STATE	FY 1997 SECTION 5311 APPORTIONMENT	FY 1997 RTAP ALLOCATION	ISTEA FY 1997 AUTHORIZED LEVELS SECTION 5311 APPORTIONMENT	ISTEA FY 1997 AUTHORIZED LEVELS RTAP ALLOCATION
Alabama	$2,774,654	$97,214	$5,200,907	$247,902
Alaska	413,761	57,041	775,567	79,511
America Samoa	58,974	11,004	110,542	14,206
Arizona	1,214,671	70,669	2,276,820	136,636
Arkansas	2,218,221	87,746	4,157,909	208,215
California	5,413,954	142,125	10,148,100	436,150
Colorado	1,155,663	69,665	2,166,214	132,428
Connecticut	1,048,295	67,838	1,964,960	124,770
Delaware	261,524	54,450	490,210	68,653
Florida	3,480,328	109,222	6,523,647	298,235
Georgia	4,056,840	119,032	7,604,279	339,354
Guam	167,885	12,857	314,689	21,974
Hawaii	455,318	57,748	853,464	82,476
Idaho	918,591	65,631	1,721,839	115,519
Illinois	3,721,924	113,333	6,976,501	315,466
Indiana	3,595,294	111,178	6,739,142	306,434
Iowa	2,312,529	89,350	4,334,683	214,941
Kansas	1,839,543	81,302	3,448,103	181,205
Kentucky	3,036,684	101,673	5,692,065	266,592
Louisiana	2,511,558	92,737	4,707,750	229,137
Maine	1,211,925	70,622	2,271,673	136,441
Maryland	1,513,030	75,746	2,836,074	157,917
Massachusetts	1,621,508	77,592	3,039,410	165,654
Michigan	4,391,321	124,723	8,231,242	363,211
Minnesota	2,526,951	92,999	4,736,604	230,235
Mississippi	2,465,977	91,961	4,622,311	225,886
Missouri	2,943,248	100,083	5,516,924	259,927
Montana	744,131	62,662	1,394,825	103,075
Nebraska	1,122,800	69,106	2,104,615	130,084
Nevada	366,577	56,238	687,125	76,146
New Hampshire	970,600	66,516	1,819,326	119,228
New Jersey	1,387,753	73,614	2,601,251	148,982
New Mexico	1,090,984	68,564	2,044,977	127,814
New York	4,885,056	133,125	9,156,716	398,427
North Carolina	5,189,372	138,303	9,727,137	420,132
North Dakota	550,318	59,364	1,031,536	89,251
Northern Marianas	54,652	10,930	102,441	13,898
Ohio	5,283,142	139,899	9,902,902	426,820
Oklahoma	2,258,489	88,431	4,233,388	211,087
Oregon	1,793,260	80,514	3,361,348	177,904
Pennsylvania	5,893,400	150,283	11,046,790	470,347
Puerto Rico	1,761,133	79,968	3,301,129	175,613
Rhode Island	225,604	53,839	422,880	66,091
South Carolina	2,597,307	94,196	4,868,481	235,253
South Dakota	670,795	61,414	1,257,362	97,844
Tennessee	3,352,826	107,052	6,284,652	289,140
Texas	7,078,748	170,452	13,268,653	554,894
Utah	508,500	58,653	953,149	86,269
Vermont	599,749	60,205	1,124,190	92,777
Virgin Islands	128,366	12,184	240,614	19,156
Virginia	2,972,605	100,582	5,571,953	262,021
Washington	2,082,867	85,442	3,904,198	198,561
West Virginia	1,771,037	80,136	3,319,693	176,319
Wisconsin	3,060,145	102,072	5,736,040	268,265
Wyoming	427,996	57,283	802,250	80,527
TOTAL	$116,158,383	$4,566,568	$217,731,250	$10,875,000

TABLE 4

FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5310 ELDERLY AND PERSONS WITH DISABILITIES APPORTIONMENTS AND ISTEA AUTHORIZED LEVELS

STATE	FY 1997 SECTION 5310 APPORTIONMENT	ISTEA FY 1997 AUTHORIZED LEVELS SECTION 5310
Alabama	$971,766	$1,678,841
Alaska	174,769	216,328
America Samoa	51,960	53,596
Arizona	859,847	1,473,466
Arkansas	686,774	1,155,872
California	5,150,324	9,346,615
Colorado	672,737	1,130,114
Connecticut	767,109	1,303,290
Delaware	250,635	355,544
District of Columbia	248,968	352,484
Florida	3,483,837	6,288,567
Georgia	1,252,413	2,193,837
Guam	131,518	136,960
Hawaii	311,791	467,767
Idaho	318,472	480,027
Illinois	2,261,194	4,044,979
Indiana	1,198,676	2,095,228
Iowa	736,367	1,246,877
Kansas	621,512	1,036,115
Kentucky	932,381	1,606,568
Louisiana	935,313	1,611,949
Maine	391,717	614,434
Maryland	939,615	1,619,842
Massachusetts	1,341,983	2,358,200
Michigan	1,938,351	3,452,554
Minnesota	952,498	1,643,483
Mississippi	667,950	1,121,329
Missouri	1,215,224	2,125,594
Montana	294,326	435,718
Nebraska	445,831	713,734
Nevada	338,305	516,422
New Hampshire	321,031	484,722
New Jersey	1,605,944	2,842,577
New Mexico	395,217	620,856
New York	3,687,196	6,661,736
North Carolina	1,420,791	2,502,815
North Dakota	254,393	362,441
Northern Marianas	51,790	53,284
Ohio	2,358,691	4,223,890
Oklahoma	808,155	1,378,611
Oregon	753,156	1,277,686
Pennsylvania	2,822,811	5,075,564
Puerto Rico	715,800	1,209,136
Rhode Island	351,504	540,641
South Carolina	782,036	1,330,681
South Dakota	272,647	395,937
Tennessee	1,142,743	1,992,589
Texas	2,914,514	5,243,842
Utah	370,061	574,695
Vermont	229,874	317,448
Virgin Islands	133,276	140,186
Virginia	1,187,751	2,075,181
Washington	1,067,908	1,855,265
West Virginia	578,418	957,036
Wisconsin	1,089,737	1,895,321
Wyoming	199,400	261,526
TOTAL	$56,059,007	$97,150,000

TABLE 5

FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5309(m)(1)(A) FIXED GUIDEWAY MODERNIZATION APPORTIONMENTS AND ISTEA AUTHORIZED LEVELS

AREA	FY 1997 SECTION 5309 (m) (1) (A) APPORTIONMENT	*ISTEA FY 1997 AUTHORIZED LEVELS SECTION 5309 (m) (1) (A) APPORTIONMENT*
AZ Phoenix	$669,108	*$1,534,418*
CA Los Angeles	10,427,516	*23,397,749*
CA Sacramento	981,632	*2,117,974*
CA San Diego	2,985,221	*6,531,165*
CA San Francisco	49,442,360	*76,538,710*
CA San Jose	4,263,280	*9,634,699*
CO Denver	782,421	*1,703,851*
CT Hartford	516,507	*1,187,072*
CT Southwestern Connecticut	31,846,888	*38,982,908*
DE Wilmington	330,779	*746,492*
DC Washington	18,344,482	*38,375,997*
FL Ft. Lauderdale	1,203,048	*2,715,185*
FL Jacksonville	37,887	*80,850*
FL Miami	3,427,932	*7,276,285*
FL Tampa	36,083	*80,900*
FL West Palm Beach	912,251	*2,043,692*
GA Atlanta	7,605,052	*15,500,314*
HI Honolulu	267,233	*628,253*
IL Chicago/Northwestern Indiana	103,902,385	*148,843,673*
LA New Orleans	2,125,226	*2,812,778*
MD Baltimore	2,896,727	*6,137,848*
MD Baltimore Commuter Rail	12,702,015	*20,150,699*
MA Boston	52,020,352	*74,847,273*
MA Lawrence-Haverhill	507,213	*1,142,620*
MI Detroit	137,537	*286,859*
MN Minneapolis	1,927,271	*4,274,095*
MO St. Louis	1,336,010	*2,854,488*
NJ Northeastern New Jersey	65,844,001	*92,369,040*
NJ Trenton	582,696	*1,193,976*
NY Buffalo	424,416	*900,914*
NY New York	260,926,381	*410,791,529*
OH Cleveland	10,658,076	*12,657,004*
OH Dayton	1,660,765	*3,783,464*
PA Philadelphia/Southern New Jersey	74,243,371	*100,872,448*
PA Pittsburgh	15,068,506	*17,515,214*
PR San Juan	699,069	*1,482,447*
OR Portland	1,164,940	*2,463,566*
RI Providence	950,200	*2,100,981*
TN Chattanooga	29,299	*66,948*
TX Dallas	313,785	*705,390*
TX Houston	2,404,861	*5,365,064*
VA Norfolk	457,758	*1,063,350*
WA Seattle	6,575,245	*14,725,664*
WA Tacoma	409,083	*955,573*
WI Madison	253,132	*560,576*
TOTAL	$754,300,000	$1,160,000,000

TABLE 6

FEDERAL TRANSIT ADMINISTRATION

FTA FISCAL YEAR 1997 SECTION 5309 NEW START ALLOCATIONS

	PROJECT LOCATION AND DESCRIPTION	FY 1997 ALLOCATION	PRIOR YEAR UNOBLIGATED ALLOCATION	TOTAL AVAILABLE
AK	Hollis- Ketchikan Ferry Project	6,345,416	0	6,345,416
AR	Little Rock- Junction Bridge Project	1,986,046	0	1,986,046
CA	Los Angeles- Metrorail- MOS-3	69,511,602	5	69,511,607
CA	Los Angeles - San Diego (LOSSAN)	1,489,534	8,397,834	9,887,368
CA	Orange County Transitway	2,979,069	0	2,979,069
CA	Sacramento- LRT Extension	5,958,137	1,975,961	7,934,098
CA	San Diego Mid-Coast Extension	1,489,534	948,000	2,437,534
CA	San Francisco- BART Extension to SFO/Tasman LRT	27,308,129	11,115,059	38,423,188
CO	Denver- Southwest Corridor LRT	1,489,534	0	1,489,534
CT	Hartford- Griffin Light Rail Project	993,023	0	993,023
FL	Fort Lauderdale- Tri-County Commuter Rail	8,937,206	0	8,937,206
FL	Jacksonville- Automated Skyway Express Extension	14,895,343	9,603,788	24,499,131
FL	Miami- North 27th Avenue Project	993,023	0	993,023
FL	Miami- Metro Dade East-West Corridor Project	1,489,534	0	1,489,534
FL	Orlando- Lynx LRT Project	1,986,046	0	1,986,046
FL	Tampa Bay Regional Rail Project	1,986,046	0	1,986,046
GA	Atlanta- North Springs Project	63,960,604	0	63,960,604
GA	Atlanta- DeKalb County Light Rail Project	656,388	0	656,388
IL	Chicago- Transit Improvements	22,343,015	0	22,343,015
IN	Northern Indiana Commuter Rail Project	496,511	0	496,511
LA	New Orleans- Canal Street Corridor Project	7,944,183	12,674,702	20,618,885
LA	New Orleans- Desire Streetcar Project	1,986,046	0	1,986,046
MA	Boston- South Boston Piers (MOS-2) Transitway	29,790,686	2	29,790,688
MD	Baltimore- Central Corridor LRT Extensions	10,188,415	0	10,188,415
MD	MARC- Commuter Rail Improvements Project	32,959,422	2	32,959,424
MN	Twin Cities Central Corridor	0	4,962,500	4,962,500
MO	Kansas City- Southtown Corridor Project	2,979,069	0	2,979,069
MO	St. Louis- Metrolink St. Clair Project	31,776,732	7,930,961	39,707,693
MO	St. Louis- Metrolink Project	13,405,809	0	13,405,809
MS	Jackson- Intermodal Corridor	5,461,626	0	5,461,626
NC	Research Triangle Park- Regional Transit Plan	1,986,046	0	1,986,046
NJ	Urban Core (Secaucus)	104,793,704	0	104,793,704
NJ	Urban Core (Hudson-Bergen)	9,930,229	0	9,930,229
NJ	Burlington-Gloucester Line	0	1,488,750	1,488,750
NJ	West Trenton- Commuter Rail	496,511	0	496,511
NY	New York- Queens Connection	34,775,661	1	34,775,662
NY	New York- Staten Island-Midtown Ferry	372,383	0	372,383
NY	New York- Whitehall Ferry Terminal	3,723,836	4,951,201	8,675,037
OH	Cleveland- Euclid Avenue Corridor/Berea Extension	0	0	0
OH	Canton-Akron-Cleveland [Northeast Ohio] Commuter Rail	3,475,580	4,198,917	7,674,497
OH	Cincinnati- Northeast/Northern Kentucky Rail	2,979,069	0	2,979,069
OK	Oklahoma City- MAPS Corridor Transit System	1,986,046	0	1,986,046
OR	Portland- Westside LRT	137,037,157	0	137,037,157
OR	Portland- South/North LRT	5,958,137	0	5,958,137
PA	Pittsburgh- Busway	9,930,229	3	9,930,232
PR	San Juan- Tren Urbano	4,716,859	0	4,716,859
TN	Memphis- Regional Rail Plan	3,017,796	0	3,017,796
TX	Dallas- North Central LRT Ext.	10,923,252	2,740,391	13,663,643
TX	Dallas- Ft. Worth RAILTRAN	15,143,599	8,905,383	24,048,982
TX	Houston- Regional Bus Plan	40,306,799	1	40,306,800
UT	Salt Lake City- South LRT Project	34,755,801	0	34,755,801
VA	Virginia Railway Express- Commuter Rail Project	2,979,069	0	2,979,069
VT	Burlington-Charlotte Commuter Rail	993,023	1,862,090	2,855,113
WI	Milwaukee- East-West Corridor	0	3,000,000	3,000,000
WA	Seattle-Renton-Tacoma Light Rail Project	2,979,069	1,332,375	4,311,444
WV	Morgantown- Personal Rapid Transit System	4,210,417	0	4,210,417
	TOTAL (All Allocations Above).....	811,256,000	86,087,926	889,012,464

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TABLE 7

FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5309(m)(1)(C) BUS ALLOCATIONS

STATE/AREA	PURPOSE	SUB-ALLOCATION	FY 1997 SECTION 5309(m)(1)(C) ALLOCATION
AZ Phoenix	Sun Tran maintenace facility		$992,500
AR Statewide	Buses and bus facilities		2,679,750
AR Little Rock	Central Arkansas transit buses and bus loading station		992,500
CA Eureka	Intermodal transportation center		992,500
CA Fairfield City	Buses		1,389,500
CA Folsom	Buses		496,250
CA Foothill	Transit bus maintenance facility		4,714,375
CA Lake Tahoe	South Shore Transportation, coordinated transit system		1,256,505
CA Long Beach	Buses and bus facilities		992,500
CA Los Angeles County (MTA)	ATTB prototype buses		3,149,202
CA Los Angeles County	Neighborhood initiative (LANI)		1,488,750
CA Mendocino County	Buses		595,500
CA North Orange County	Buses		198,500
CA Norwalk	Buses and bus facilities		992,500
CA Riverside County	Buses and bus facilities		992,500
CA San Francisco	Buses		4,242,938
CA San Joaquin	RTD downtown transit center (livable communities)		2,729,375
CA San Ysidro Border	Border intermodal center		992,500
CA Santa Barbara (MTD)	Buses and bus facilities		1,985,000
CA Santa Cruz (MTD)	Bus facility		1,985,000
CA Sonoma County	Park-and-ride facilities		992,500
CA Thousand Oaks	Multimodal center		595,500
CA Yolo County	Buses		1,985,000
CO Fort Collins and Greeley	Buses		992,500
CT Bridgeport	Buses and bus facilities		992,500
DE Statewide	Buses and bus facilities		6,947,500
FL Metropolitan Dade County	Buses and bus facilities		4,962,500
FL Miami Beach	Electric battery buses		992,500
FL Orlando	LYNX Buses		4,466,250
FL Palm Beach County	Buses and bus facilities		992,500
FL Tampa (Hillsborough area RTD)	HARTline buses		2,779,000
FL Volusia County (Votran)	Buses		1,488,750
FL Ybor	Buses and bus facilities		992,500
GA Chatham	Bus facility		1,052,050
GA MARTA	Buses		1,985,000
IA Cedar Rapids	Park and ride lots		1,183,060
IA Cedar Rapids	Hybrid electric bus consortium		886,302
IA Des Moines			1,183,060
IA Fort Dodge	Park and ride facility		688,160
IA Statewide	Buses and bus facilities		3,693,668
IA Iowa City			849,342
IA Ottumwa			60,940
IA Sioux City	Includes intermodal center		2,143,800
IA Waterloo	Intermodal bus facility		660,012

TABLE 7

FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5309(m)(1)(C) BUS ALLOCATIONS

STATE/AREA	PURPOSE	SUB-ALLOCATION	FY 1997 SECTION 5309(m)(1)(C) ALLOCATION
IA Iowa Department of Transportation	State regions 6,13,14,15 & 16		$1,261,368
	Region 6	$10,024	
	Region 13	384,693	
	Region 14	292,589	
	Region 15	326,334	
	Region 16	247,728	
IL Statewide*	Buses and bus facilities		10,917,500
Champaign-Urbana	Replacement buses	833,700	
Chicago (CTA)	New bus communications system	4,962,500	
Madison County	Replacement buses	952,800	
Pace	Buses	1,756,725	
Rock Island	Replacement buses	952,800	
Rural Paratransit	Buses	476,400	
Springfield	Replacement buses	952,800	
IN Statewide	Buses and bus facilities		3,721,875
IN Indianapolis (metro)	New buses		992,500
IN South Bend	Intermodal facility		5,458,750
KS Statewide	Buses and bus facilities		992,500
KS Johnson City	Bus maintenance center		2,183,500
KY Statewide	Buses and bus facilities		3,970,000
KY Owensboro	Vans		99,250
LA Statewide	Buses and bus facilities		16,376,250
Alexandria	Buses	978,605	
Baton Rouge	Buses	1,313,077	
DOTD	Vans	956,770	
Jefferson Parish	Buses	1,969,120	
Lafayette	Intermodal facility	746,360	
Lake Charles	Buses	307,675	
Monroe	Buses	292,788	
New Orleans	Buses and bus facilities	8,952,350	
Shreveport	Bus facility	859,505	
MD Statewide	Buses and bus facilities		4,962,500
MA Boston	South Station intermodal center		992,500
MA Hyannis/Cape Cod	Intermodal transportation center		3,225,625
MA Lowell	Gallagher transportation terminal		992,500
MA Springfield	Union Station intermodal facility		744,375
MA Worcester	Union Station		2,977,500
MI Statewide	Buses and bus facilities (includes ISTEA earmark)		14,391,250
Dearborn	Intermodal facility	992,500	
Detroit (SMART)	Buses and facilities	1,985,000	
Detroit	Intermodal facility	1,985,000	
Flint	Bus facilities	1,985,000	

TABLE 7

FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5309(m)(1)(C) BUS ALLOCATIONS

STATE/AREA	PURPOSE	SUB-ALLOCATION	FY 1997 SECTION 5309(m)(1)(C) ALLOCATION
MI Statewide (cont'd)			
For distribution by the State of MI	Buses and bus facilities	$2,610,275	
Grand Rapids (GRATA)	Bus facilities	1,985,000	
Kalamazoo	Buses and bus facilities	992,500	
Kalkaska	Bus facilities	635,200	
Lansing	Bus facility	1,220,775	
MN Minneapolis/St. Paul (MCTO)	Buses and bus facilities		$5,955,000
MS Jackson	Buses		992,500
MS Jackson	Downtown multimodal transit center		3,473,750
MO Kansas City (KCATA)	Buses		2,630,125
MO Kansas City	Union Station intermodal		6,451,250
MO Kansas City	Replacement trolleys (Kansas City Trolley Corporation)		317,600
MO Statewide	Buses and bus facilities		9,180,625
MO St. Louis	Buses and bus facilities		1,736,875
NV Clark County	Bus facilities		3,275,250
NV Reno (RTC)	Buses		1,721,988
NJ New Jersey Transit	Clean Air Act bus fleet improvements		2,977,500
NM Albuquerque	URICA bus project		1,985,000
NY Brooklyn, Bronx, Manhattan	Alternative bus fuels fueling facilities		5,955,000
NY Broome County	Buses		992,500
NY Buffalo	Crossroads intermodal station		992,500
NY Chemung County	Intermodal center		1,488,750
NY Elmira	Buses and bus facilities		992,500
NY Long Island	Bus alternatives fuels fueling facilities		1,885,750
NY New Rochelle	Intermodal facility		1,240,625
NY New York City	Natural gas buses		9,925,000
NY Rochester-Genesse RTA	Buses		1,736,875
NY Syracuse	Buses		1,985,000
NY Utica	Buses support vehicles		1,191,000
NY Westchester County	Bus facilities		496,250
NC Statewide	Buses and bus facilities		3,970,000
ND Bismarck-Mandan (Bis-Man Transit)	Intermodal center		1,488,750
OH Statewide	Buses		27,293,750
OH Cleveland	Triskett bus garage and facilities (Including CITME)		1,488,750
OR Eugene	Lane Transit District buses and station		2,530,875
OR Central City	Streetcar		4,962,500
OR Hood River	Buses		173,688
OR Salem	Downtown transit center		1,836,125
OR Portland, South	Buses and south bus mall extension		8,932,500
OR Wilsonville	Transit vehicles		248,125
PA Statewide	Buses and bus facilities		1,429,200
PA Altoona (ISTEA earmark)	Bus testing		2,977,500
PA Armstrong County MID-County	Buses and bus facilities		260,035
PA Berks Area Reading Transit	Intermodal facility		397,000

TABLE 7

FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5309(m)(1)(C) BUS ALLOCATIONS

STATE/AREA	PURPOSE	SUB-ALLOCATION	FY 1997 SECTION 5309(m)(1)(C) ALLOCATION
PA Erie	Intermodal complex		$1,985,000
PA Indiana County	Buses		674,900
PA Johnstown (Cambria County)	Buses and bus facilities		1,021,282
PA Lehigh/North Hampton Transportation	Buses		397,000
PA Mid Mon Valley Transit	Buses		79,400
PA Philadelphia	North Philadelphia intermodal center		992,500
PA Philadelphia	Alternative fueled vehicles		3,970,000
PA SEPTA			7,940,000
PA Scranton	Buses and bus facilities		992,500
PA Somerset County	Vans		119,100
PA Williamsport	Buses and bus facilities		1,985,000
SC Spartanburg	Intermodal facility		1,488,750
TN Statewide	Buses and bus facilities		2,481,250
TX Statewide	Buses and bus facilities		2,183,500
TX Brazos Valley	Woodlands town center project		1,339,875
TX Corpus Christi	Buses and bus facilities		992,500
TX El Paso	Buses and bus facilities		2,481,250
TX Galveston	Trolley maintenance		496,250
TX Liberty, Montgomery, Polk Counties	Service expansion		2,977,500
UT Salt Lake City	2002 Winter Olympics buses and facilities		5,558,000
UT Salt Lake City	2002 Winter Olympics intermodal centers		5,458,750
UT Logan	Buses and bus facilities		2,382,000
VT Statewide	Buses and bus facilities		1,240,625
VT Burlington	Multimodal center		1,488,750
VT Rutland	Intermodal center		694,750
VT Urban & Rural	Buses and bus facilities		2,729,375
VA Reston	Internal bus system, buses		496,250
VA Richmond	Downtown intermodal station		9,925,000
VA Virginia Beach	Intermodal facility		992,500
WA Bremerton	Buses and bus facilities		1,985,000
WA Chelan-Douglas	Multimodal center-Amtrak platform		992,500
WA Everett	Intermodal center		2,977,500
WA Port Angeles	Buses and bus facilities		992,500
WA Seattle Metro/King County	Multimodal		3,970,000
WA Tacoma	Tacoma Dome		4,466,250
WA Thurston County	Intercity transit buses		992,500
WV Charleston	Renovate maintenance facility		3,156,150
WI Statewide	Buses and bus facilities		11,810,750
WY Freemont County	Shoshone and Arapahoe Nation's buses and facility		992,500
TOTAL			$377,150,000

* Of the total amount allocated to the State of Illinois, $29,775 is not included in the sub-allocations.

TABLE 7A

FEDERAL TRANSIT ADMINISTRATION

PRIOR YEAR UNOBLIGATED SECTION 5309 (m)(1)(C) BUS ALLOCATIONS

	STATE/AREA	PRIOR YEAR SECTION 5309 (m)(1)(C) UNOBLIGATED ALLOCATION
FY 1996		
	AR Statewide	$3,964,000
	CA Coachella Valley	496,250
	CA Long Beach	1,488,750
	CA San Diego	4,674,500
	CA San Francisco	3,233,065
	CA Sonoma County	1,240,625
	CT Norwich	1,488,750
	GA Atlanta	3,721,875
	HI Honolulu	3,970,000
	IL Statewide	1,759,702
	IN State	608,069
	IN Gary/Hammond	258,050
	IN South Bend	2,484,678
	IA Waterloo	664,975
	IA Cedar Rapids	1,191,000
	KY Lexington	992,500
	LA New Orleans	2,977,500
	LA St. Bernard Parish	1,488,750
	MD MTA	12,902,500
	MN Minneapolis	7,443,750
	MO Kansas City	6,451,250
	MO Statewide	6,947,500
	NY Albany	4,962,500
	NY Buffalo	496,250
	NY Garden State Parkway	1,141,375
	NY Long Island	1,488,750
	NY Rensselaer	7,433,750
	NY Rochelle	744,375
	NY Syracuse	1,985,000
	NY Westchester County	2,233,125
	NC State	4,962,500
	OH State	2,200,000
	PA Altoona	992,500
	PA Philadelphia	992,500
	PA Erie	3,970,000
	TN Nashville	297,750
	TX El Paso	5,161,000
	VA Richmond	4,962,500
	VT Statewide	2,977,500

TABLE 7A

FEDERAL TRANSIT ADMINISTRATION

PRIOR YEAR UNOBLIGATED SECTION 5309 (m)(1)(C) BUS ALLOCATIONS

	STATE/AREA	PRIOR YEAR SECTION 5309 (m)(1)(C) UNOBLIGATED ALLOCATION
FY 1996 (cont'd)		
	VT Marble Valley	$612,500
	WA Everett	3,473,750
	WA King County/Seattle	8,188,125
	WI Statewide	5,129,240
FY 1995		
	CT Norwich	$2,000,000
	FL Orlando	828,400
	IL Statewide	2,724,000
	IA Cedar Rapids	2,550,000
	LA New Orleans	2,000,000
	MI Detroit	4,000,000
	MO Kansas City	3,760,000
	NJ Camden	150,000
	NM Albuquerque	3,750,000
	NY Bronx	1,000,000
	OR Albany	86,000
	TX El Paso	2,810,613
	TX El Paso	1,500,000
	VA Northern Virginia Dulles	950,000
FY 1994		
	NJ Camden	$800,000
	IN South Bend	3,428
	TOTAL	$163,765,470

TABLE 8

FEDERAL TRANSIT ADMINISTRATION

FY 1997 SECTION 5303 METROPOLITAN PLANNING PROGRAM AND SECTION 5313(b) STATE PLANNING AND RESEARCH PROGRAM

STATE	FY 1997 METROPOLITAN PLANNING PROGRAM APPORTIONMENT	FY 1997 STATE PLANNING AND RESEARCH PROGRAM APPORTIONMENT	*ISTEA FY 1997 AUTHORIZED LEVELS*	
			SECTION 5303 APPORTIONMENT	*SECTION 5313(b) APPORTIONMENT*
Alabama	$350,159	$90,647	*$857,286*	*$229,922*
Alaska	160,691	41,396	*391,502*	*105,000*
Arizona	631,094	130,849	*1,559,149*	*331,894*
Arkansas	160,691	41,396	*391,502*	*105,000*
California	6,781,265	1,254,602	*16,686,764*	*3,182,251*
Colorado	521,298	117,144	*1,273,462*	*297,133*
Connecticut	462,884	120,981	*1,144,171*	*306,864*
Delaware	160,691	41,396	*391,502*	*105,000*
District/Col	215,632	41,396	*527,817*	*105,000*
Florida	2,156,865	501,405	*5,337,057*	*1,271,797*
Georgia	767,987	160,638	*1,889,333*	*407,454*
Hawaii	160,691	41,396	*391,502*	*105,000*
Idaho	160,691	41,396	*391,502*	*105,000*
Illinois	2,343,651	417,706	*5,719,120*	*1,059,498*
Indiana	569,612	132,656	*1,388,423*	*336,477*
Iowa	179,331	46,440	*439,206*	*117,794*
Kansas	206,476	50,182	*507,734*	*127,285*
Kentucky	249,175	62,905	*608,169*	*159,556*
Louisiana	438,000	109,764	*1,050,948*	*278,413*
Maine	160,691	41,396	*391,502*	*105,000*
Maryland	932,101	176,442	*2,272,317*	*447,540*
Massachusetts	1,134,990	233,044	*2,771,517*	*591,109*
Michigan	1,470,219	286,354	*3,570,467*	*726,327*
Minnesota	594,005	116,805	*1,449,807*	*296,272*
Mississippi	160,691	41,396	*391,502*	*105,000*
Missouri	695,407	137,093	*1,602,949*	*347,731*
Montana	160,691	41,396	*391,502*	*105,000*
Nebraska	160,691	41,396	*391,502*	*105,000*
Nevada	173,586	44,885	*424,502*	*113,851*
New Hampshire	160,691	41,396	*391,502*	*105,000*
New Jersey	1,984,402	326,607	*4,852,183*	*828,428*
New Mexico	160,691	41,396	*391,502*	*105,000*
New York	4,032,593	695,432	*9,853,166*	*1,763,942*
North Carolina	473,443	123,797	*1,170,807*	*314,008*
North Dakota	160,691	41,396	*391,502*	*105,000*
Ohio	1,383,816	327,958	*3,372,951*	*831,856*
Oklahoma	256,730	66,722	*631,022*	*169,239*
Oregon	290,417	69,960	*708,810*	*177,451*
Pennsylvania	1,909,473	355,080	*4,374,628*	*900,650*
Rhode Island	165,658	41,396	*391,502*	*105,000*
South Carolina	268,740	70,289	*664,753*	*178,285*
South Dakota	160,691	41,396	*391,502*	*105,000*
Tennessee	421,256	109,271	*1,033,425*	*277,162*
Texas	2,708,092	560,258	*6,650,538*	*1,421,077*
Utah	248,024	65,008	*614,812*	*164,891*
Vermont	160,691	41,396	*391,502*	*105,000*
Virginia	885,950	188,674	*2,187,535*	*478,565*
Washington	710,222	158,375	*1,743,544*	*401,714*
West Virginia	160,691	41,396	*391,502*	*105,000*
Wisconsin	557,792	121,425	*1,220,712*	*307,992*
Wyoming	160,691	41,396	*391,502*	*105,000*
Puerto Rico	431,242	104,702	*1,060,882*	*265,572*
	$40,172,643	$8,279,228	*$97,875,500*	*$21,000,000*

TABLE 9

FEDERAL HIGHWAY ADMINISTRATION

FY 1997 METROPOLITAN PLANNING PROGRAM
AND FY 1997 STATE PLANNING AND RESEARCH PROGRAM

STATE	ESTIMATED FY 1997 METROPOLITAN PLANNING PROGRAM APPORTIONMENT	ESTIMATED FY 1997 STATE PLANNING AND RESEARCH PROGRAM APPORTIONMENT
Alabama	$1,728,566	$5,094,000
Alaska	789,394	4,145,000
Arizona	2,495,191	3,778,000
Arkansas	789,394	3,269,000
California	23,924,292	25,461,000
Colorado	2,233,856	4,013,000
Connecticut	2,307,018	5,345,000
Delaware	789,394	1,371,000
Distr. of Col.	789,394	1,551,000
Florida	9,561,423	11,602,000
Georgia	3,063,258	7,589,000
Hawaii	789,394	2,404,000
Idaho	789,394	2,146,000
Illinois	7,965,348	10,647,000
Indiana	2,529,649	5,664,000
Iowa	885,581	4,026,000
Kansas	956,933	3,660,000
Kentucky	1,199,548	4,331,000
Louisiana	2,093,123	5,011,000
Maine	789,394	1,667,000
Maryland	3,364,623	4,620,000
Massachusetts	4,443,983	12,710,000
Michigan	5,460,559	7,546,000
Minnesota	2,227,388	5,012,000
Mississippi	789,394	3,708,000
Missouri	2,614,258	6,997,000
Montana	789,394	2,987,000
Nebraska	789,394	2,764,000
Nevada	855,933	2,019,000
New Hampshire	789,394	1,621,000
New Jersey	6,228,157	7,646,000
New Mexico	789,394	3,362,000
New York	13,261,391	15,642,000
N. Carolina	2,360,725	7,388,000
N. Dakota	789,394	1,969,000
Ohio	6,253,930	11,536,000
Oklahoma	1,272,345	3,910,000
Oregon	1,334,082	3,179,000
Pennsylvania	6,771,121	12,192,000
Rhode Island	789,394	1,502,000
S. Carolina	1,340,358	3,787,000
S. Dakota	789,394	2,169,000
Tennessee	2,083,719	6,478,000
Texas	10,683,717	18,953,000
Utah	1,239,659	2,468,000
Vermont	789,394	1,471,000
Virginia	3,597,869	5,885,000
Washington	3,020,103	6,389,000
West Virginia	789,394	3,169,000
Wisconsin	2,315,495	5,585,000
Wyoming	789,394	2,169,000
Puerto Rico	1,996,582	1,721,000
Total	$157,878,875	$291,328,000

TABLE 10

Federal Transit Administration - Unit Values of Data
Fiscal Year 1997 Formula Grant Apportionments

Section 5307 Urbanized Area Formula Program - Bus Tier

Urbanized Areas Over 1,000,000:

Population	$2.09112649
Population x Density	$0.00053634
Bus Revenue Vehicle Mile	$0.29661622

Urbanized Areas Under 1,000,000:

Population	$1.88979937
Population x Density	$0.00083226
Bus Revenue Vehicle Mile	$0.38184824

Bus Incentive (PM denotes Passenger Mile):

Bus PM x Bus PM = / Operating Cost	$0.00353153

Section 5307 Urbanized Area Formula Program - Fixed Guideway Tier

Fixed Guideway Revenue Vehicle Mile	$0.40702226
Fixed Guideway Route Mile	$23,377
- Commuter Rail Floor $4,277,721	

Fixed Guideway Incentive:

Fixed Guideway PM x Fixed Guideway PM = / Operating Cost	$0.00038296
- Commuter Rail Incentive Floor $196,415	

Section 5307 Urbanized Area Formula Program - Areas Under 200,000

Population	$3.41199253
Population x Density	$0.00170497

Section 5311 Nonurbanized Area Formula Program

Areas Under 50,000

Population	$1.26085061

Section 5309(m)(1)(A) Capital Program - Fixed Guideway Modernization

	Tier 3	Tier 4
Legislatively Specified Areas:		**All Areas:**
Revenue Vehicle Mile	$0.03043440	$0.13683130
Route Mile	$2,212.43	$7,832.52
Other Areas:		
Revenue Vehicle Mile	$0.16377360	
Route Mile	$4,772.78	

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federal register

Monday
October 7, 1996

Part III

Department of Transportation

Federal Transit Administration

Fiscal Year 1997 Annual List of Certifications and Assurances for Federal Transit Administration Grants and Cooperative Agreements; Notice

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Fiscal Year 1997 Annual List of Certifications and Assurances for Federal Transit Administration Grants and Cooperative Agreements

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice.

SUMMARY: This Notice contains FTA's comprehensive compilation of the Federal Fiscal Year 1997 certifications and assurances to be used in connection with all Federal assistance programs administered by FTA during Federal Fiscal Year 1997. (See Appendix A.) These certifications and assurances include all annual certifications required by 49 U.S.C. 5307(d)(1) for FTA's Urbanized Area Formula Program as well as other certifications and assurances needed for compliance with various other Federal statutes and regulations affecting FTA's assistance programs.

EFFECTIVE DATE: October 7, 1996.

FOR FURTHER INFORMATION CONTACT: Linda Watkins Sorkin, Office of the Chief Counsel, Federal Transit Administration, (202) 366–1936; or contact FTA staff in the appropriate Regional Office listed below.

Region 1: Boston

States served: Maine, New Hampshire, Vermont, Connecticut, Rhode Island, and Massachusetts, Telephone # 617–494–2055.

Region 2: New York

States served: New York, New Jersey, and Virgin Islands, Telephone # 212–264–8162.

Region 3: Philadelphia

States served: Pennsylvania, Delaware, Maryland, Virginia, West Virginia, and District of Columbia, Telephone # 215–656–6900.

Region 4: Atlanta

States served: Kentucky, North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Tennessee, and Puerto Rico, Telephone # 404–562–3500.

Region 5: Chicago

States served: Minnesota, Wisconsin, Michigan, Illinois, Indiana, and Ohio, Telephone # 312–353–2789.

Region 6: Dallas/Ft. Worth

States served: Arkansas, Louisiana, Oklahoma, Texas, and New Mexico, Telephone # 817–860–9663.

Region 7: Kansas City

States served: Missouri, Iowa, Kansas, and Nebraska, Telephone # 816–523–0204.

Region 8: Denver

States served: Colorado, Utah, Wyoming, Montana, North Dakota, South Dakota, Arizona,[1] and Nevada,[1]

Region 9: San Francisco

States served: California, Hawaii, Guam, American Samoa, and the Northern Mariana Islands, Telephone # 415–744–3133.

Region 10: Seattle

States served: Idaho, Oregon, Washington, and Alaska, Telephone # 206–220–7954.

SUPPLEMENTARY INFORMATION: Before FTA may award a Federal grant or cooperative agreement, the applicant must provide to FTA all certifications and assurances required by Federal laws and regulations for the applicant or its project.

This Notice provides the text of certifications and assurances that may be required by law for the various Federal assistance programs administered by FTA including the Capital Program, the Urbanized Area Formula Program; the Nonurbanized Area Formula Program, the Metropolitan Planning Program, the Rural Transit Assistance Program, the Elderly and Persons With Disabilities Program, the Human Resource Program, the National Training Institute Program, the State Planning and Research Program, and the National Planning and Research Program, all codified at 49 U.S.C. chapter 53. When administering Federal assistance programs authorized by other Federal statutes, such as Title 23, United States Code, FTA uses these same certifications and assurances during Federal Fiscal Year 1997.

This Notice provides the applicant with a single Signature Page on which the applicant and its attorney certifies compliance with all certifications and assurances applicable to each grant or cooperative agreement for which the applicant wishes to apply in Federal Fiscal Year 1997. (See Appendix B.)

FTA is expanding the use of the two electronic programs for applicants introduced in 1995. The On-Line Program is offered to applicants through the Grant Management Information System (GMIS). This is a computerized system designed to assist the FTA grantee or recipient of a cooperative agreement in managing its FTA assisted projects and their budgets. All applicants are encouraged to participate in the On-Line Program, which includes the opportunity to certify compliance electronically for all certifications and assurances selected among those in Appendix A. The Electronic Grant Making and Management initiative (EGMM) pilot program also initiated in Federal Fiscal Year—1995 has proved so successful in reducing time and paper that EGMM will continue to be offered to more applicants. Applicants may contact their Regional Office shown above for more information.

This 1997 Annual Certifications and Assurances document contains changes to the previous year's Federal Register publication. One change is the addition of Category III, *Effects On Private Mass Transportation Companies.* Please read this category in Appendix A before certifying. Another change occurs at Category XV, *Certifications and Assurances for the State Infrastructure Bank Program*. This new category concerns grant applicants requesting Federal assistance for deposit in the Transit Account of the State Infrastructure Bank (SIB). Additional changes have been made to the Annual Certifications and Assurances, which may include clarification and reference sources.

In Category I–G, *Assurance of Nondiscrimination on the Basis of Disability,* a revision occurred in the regulation for compliance, CFR 49 Part 27. (see Federal Register of May 21, 1996, p 25416.) This 1997 certification therefore either assures FTA of the applicant's full implementation of ADA paratransit service requirements by January 26, 1997 with no further need to submit annual plan update; or, if not in compliance, of the applicant's intent to submit a 1997 plan update with a valid request for a time extension, in order to remain eligible for Federal funding. Each applicant is advised to read the entire 1997 Certifications and Assurances to be confident of their responsibilities and committments. The applicant may signify compliance with all Categories by placing a single ''X'' in the appropriate space at the top of the Signature Selection Page in Appendix A. However, the applicant's Attorney Affirmation continues to be required as indicated on the Signature Page at the end of Appendix B, regardless of the applicant's selection of a single selection for all fifteen Categories or options selection from the fifteen Categories.

FTA directs your attention to FTA Circular 9300.1, ''Capital Program Grant Application Instructions,'' which was

[1] Transportation projects for these states are administered by Region 8 but are geographically in Region 9) Telephone # 304–844–3242.

published on September 29, 1995. That circular contains a previous draft version of the Annual Certifications and Assurances which includes some but not all of the most current and valid changes. Therefore the provisions of this Notice supersede conflicting statements in that circular. Note especially that the Applicant must use the most current Signature Pages shown in this *Federal Fiscal Year 1997* Federal Register document or provided concurrently through the EGMM initiative discussed above.

Background

With the publication of the Federal Fiscal Year 1995 counterpart of this Notice, certifications and assurances for Federal assistance programs administered by FTA were for the first time consolidated into one document. This marked the beginning of an effort to assist applicants in reducing time and paper work in certifying compliance with various Federal laws and regulations. It coincided with the On-Line Program and the EGMM initiative described above, which also reduced the time and paper required to process an application.

FTA intends to continue publishing this document annually with any changes or additions specifically highlighted, in conjunction with its publication of the FTA annual apportionment Notice, which allocates funds in accordance with the latest U.S. Department of Transportation (U.S. DOT) annual appropriations act.

Procedures

Following is a detailed compilation of Certifications and Assurances (Appendix A), followed by a Signature Page (Appendix B). The Signature Page is to be signed by the applicant's authorized representative and its attorney (the attorney's current affirmation may be on file in some instances), and sent to the appropriate FTA Regional office by: (1) The first-quarter application submission date published in FTA's Federal Fiscal Year 1997 apportionment announcement; or (2) with the applicant's first Federal assistance application in Federal Fiscal Year 1997.

The Signature Page, when properly signed and submitted to FTA, assures FTA that the applicant intends to comply with the requirements for the specific program involved. Both sides of the Signature Page must be completed, first by marking where appropriate with an ''X'' on the category selection side, and then signifying compliance by signing the signature side. (See Appendix B.)

An applicant participating in the On-Line Program or the EGMM Program described above, may submit its Signature Page (both the selection side and the signature side) electronically. The applicant should not hesitate to consult with the appropriate Regional Office or Headquarters Office before submitting its certifications and assurances.

References: 49 U.S.C. chapter 53, Title 23 U.S.C., 42 U.S.C. 4151, Title VI and Title VII of the Civil Rights Act, FTA regulations under 49 CFR, and FTA Circulars.

Issued On: September 30, 1996.

Gordon J. Linton,

Administrator.

BILLING CODE 4910–57–P

Appendix A

FEDERAL FISCAL YEAR 1997 CERTIFICATIONS AND ASSURANCES FOR FEDERAL TRANSIT ADMINISTRATION ASSISTANCE PROGRAMS

Each Applicant is requested to provide as many of the following certifications and assurances as possible to cover the various types of Federal assistance programs for which the Applicant intends to seek Federal assistance from FTA in Federal Fiscal Year 1997. A state making certifications and assurances on behalf of its prospective subrecipients is expected to obtain sufficient documentation from those subrecipients as necessary for the state to make informed certifications and assurances. The fifteen categories of certifications and assurances are listed by Roman numerals I through XV on the other side of the Signature Page document. Categories II through XV will apply to some, but not all applicants. The categories correspond to the following descriptions of circumstances mandating submission of specific certifications, assurances, or agreements:

I. CERTIFICATIONS AND ASSURANCES REQUIRED OF EACH APPLICANT

Each Applicant for Federal assistance awarded by FTA must make all certifications and assurances in this Category I. Accordingly, FTA may not award any Federal assistance until the Applicant provides assurance of compliance by selecting Category I on the Signature Page at the end of this document.

A. Authority of Applicant and Its Representative

The authorized representative of the Applicant and legal counsel who sign these certifications, assurances, and agreements attest that both the Applicant and its authorized representative have adequate authority under state and local law and the by-laws or internal rules of the Applicant organization to:
(1) Execute and file the application for Federal assistance on behalf of the Applicant,
(2) Execute and file the required certifications, assurances, and agreements on behalf of the Applicant binding the Applicant, and
(3) Execute grant and cooperative agreements with FTA on behalf of the Applicant.

B. Standard Assurances

The Applicant assures that it will comply with all applicable Federal statutes, regulations, executive orders, FTA circulars, and other Federal administrative requirements in carrying out any grant or cooperative agreement awarded by FTA. The Applicant acknowledges that it is under a continuing obligation to comply with the terms and conditions of the grant or cooperative agreement issued for its approved project with FTA. The Applicant understands that Federal laws, regulations, policies, and administrative practices might be modified from time to time and affect the implementation of the project. The Applicant agrees that the most recent Federal requirements will apply to the project, unless FTA issues a written determination otherwise.

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C. Debarment, Suspension, and Other Responsibility Matters -- Primary Covered Transactions

As required by U.S. DOT regulations on Governmentwide Debarment and Suspension (Nonprocurement) at 49 CFR 29.510:

(1) The Applicant (Primary Participant) certifies to the best of its knowledge and belief, 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 proposal been convicted of or had a civil judgment 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 listed in paragraph (2) of this certification; and

(d) Have not within a three-year period preceding this certification had one or more public transactions (Federal, state, or local) terminated for cause or default.

(2) The Applicant also certifies that if, later, it becomes aware of any information contradicting the statements of paragraphs (a) through (d) above, it will promptly provide that information to FTA.

(3) If the Applicant (Primary Participant) is unable to certify to the statements within paragraphs (1) and (2) above, it shall indicate so on its Signature Page and provide a written explanation to FTA.

D. Drug-Free Workplace Certification

As required by U.S. DOT regulations on Drug-Free Workplace Requirements (Grants) at 49 CFR 29.630, the Applicant certifies that it will provide a drug-free workplace by:

(1) Publishing a statement notifying its employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the Applicant's workplace and specifying the actions that will be taken against its employees for violation of that prohibition;

(2) Establishing an ongoing drug-free awareness program to inform its employees about: (a) the dangers of drug abuse in the workplace; (b) the Applicant's policy of maintaining a drug-free workplace; (c) any available drug counseling, rehabilitation, and employee assistance programs; and (d) the penalties that may be imposed upon its employees for drug abuse violations occurring in the workplace;

(3) Making it a requirement that each of its employees to be engaged in the performance of the grant or cooperative agreement be given a copy of the statement required by paragraph (1);

(4) Notifying each of its employees in the statement required by paragraph (1) that, as a condition of employment financed with Federal assistance provided by the grant or cooperative agreement, the employee will: (a) abide by the terms of the statement, and (b) notify the employer (Applicant)

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in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than 5 calendar days after that conviction;
(5) Notifying FTA in writing, within 10 calendar days after receiving notice required by paragraph (4)(b) above from an employee or otherwise receiving actual notice of that conviction. The Applicant, which is the employer of any convicted employee must provide notice, including position title, to every project officer or other designee on whose project activity the Applicant's convicted employee was working. Notice shall include the identification number(s) of each affected grant or cooperative agreement.
(6) Taking one of the following actions within 30 calendar days of receiving notice under paragraph (4)(b) above with respect to any employee who is so convicted: (a) by taking appropriate personnel action against that employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended, or (b) by requiring that 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;
(7) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (1), (2), (3), (4), (5), and (6) above.
The Applicant has or will provide to FTA a list identifying its headquarters location and each workplace it maintains in which project activities supported by FTA are conducted.

E. Intergovernmental Review Assurance

The Applicant assures that each application for Federal assistance submitted to FTA has been or will be submitted, as required by each state, for intergovernmental review to the appropriate state and local agencies. Specifically, the Applicant assures that it has fulfilled or will fulfill the obligations imposed on FTA by U.S. DOT regulations, "Intergovernmental Review of Department of Transportation Programs and Activities," 49 CFR part 17.

F. Nondiscrimination Assurance

As required by 49 U.S.C. 5332, Title VI of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000d, and U.S. DOT regulations, "Nondiscrimination in Federally-Assisted Programs of the Department of Transportation -- Effectuation of Title VI of the Civil Rights Act," 49 CFR part 21 at 21.7, the Applicant assures that it will comply with all requirements of 49 CFR part 21; FTA Circular 4702.1, "Title VI Program Guidelines for Federal Transit Administration Recipients"; and other applicable directives, so that no person in the United States, on the basis of race, color, national origin, creed, sex, or age will be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination in any program or activity (particularly in the level and quality of transportation services and transportation-related benefits) for which the Applicant receives Federal assistance awarded by the U.S. DOT or FTA as follows:
(1) The Applicant assures that each project will be conducted, property acquisitions will be undertaken, and project facilities will be operated in accordance with all applicable requirements of 49 U.S.C. 5332 and 49 CFR part 21, and understands that this assurance extends to its entire facility and to facilities operated in connection with the project.

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(2) The Applicant assures that it will take appropriate action to ensure that any transferee receiving property financed with Federal assistance derived from FTA will comply with the applicable requirements of 49 U.S.C. 5332 and 49 CFR part 21.
(3) The Applicant assures that it will promptly take the necessary actions to effectuate this assurance, including notifying the public that complaints of discrimination in the provision of transportation-related services or benefits may be filed with U.S. DOT or FTA. Upon request by U.S. DOT or FTA, the Applicant assures that it will submit the required information pertaining to its compliance with these requirements.
(4) The Applicant assures that it will make any changes in its 49 U.S.C. 5332 and Title VI implementing procedures as U.S. DOT or FTA may request.
(5) As required by 49 CFR 21.7(a)(2), the Applicant will include appropriate clauses in each third party contract or subagreement to impose the requirements of 49 CFR part 21 and 49 U.S.C. 5332, and include appropriate provisions imposing those requirements in deeds and instruments recording the transfer of real property, structures, improvements.

G. Assurance of Nondiscrimination on the Basis of Disability

As required by U.S. DOT regulations, "Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting from Federal Financial Assistance," at 49 CFR part 27, implementing the Rehabilitation Act of 1973, as amended, and the Americans with Disabilities Act of 1990, as amended, the Applicant assures that, as a condition to the approval or extension of any Federal assistance awarded by FTA to construct any facility, obtain any rolling stock or other equipment, undertake studies, conduct research, or to participate in or obtain any benefit from any program administered by FTA, no otherwise qualified person with a disability shall be, solely by reason of that disability, excluded from participation in, denied the benefits of, or otherwise subjected to discrimination in any program or activity receiving or benefiting from Federal assistance administered by the FTA or any entity within U.S. DOT. The Applicant assures that project implementation and operations so assisted will comply with all applicable requirements of U.S. DOT regulations implementing the Rehabilitation Act of 1973, as amended, and the Americans with Disabilities Act of 1990, as amended, at 49 CFR parts 27, 37, and 38, and any applicable regulations and directives issued by other Federal departments or agencies.

H. Procurement Compliance

The Applicant certifies that its procurements and procurement system will comply with all applicable requirements imposed by Federal laws, executive orders, or regulations and the requirements of FTA Circular 4220.1D, "Third Party Contracting Requirements," and other implementing requirements FTA may issue. The Applicant certifies that it will include in its contracts financed in whole or in part with FTA assistance all clauses required by Federal laws, executive orders, or regulations, and will ensure that each subrecipient and contractor will also include in its subagreements and contracts financed in whole or in part with FTA assistance all applicable clauses required by Federal laws, executive orders, or regulations.

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II. LOBBYING CERTIFICATION REQUIRED FOR EACH APPLICATION EXCEEDING $100,000

An Applicant that submits, or intends to submit this fiscal year, an application for Federal assistance exceeding $100,000 must provide the following certification. FTA may not provide Federal assistance for an application exceeding $100,000 until the Applicant provides this certification by selecting Category II on the Signature Page.

A. As required by U.S. DOT regulations, "New Restrictions on Lobbying," at 49 CFR 20.110, the Applicant's authorized representative certifies to the best of his or her knowledge and belief that for each application for a Federal assistance exceeding $100,000: (1) No Federal appropriated funds have been or will be paid, by or on behalf of the Applicant, 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 pertaining to the award of any Federal assistance, or the extension, continuation, renewal, amendment, or modification of any Federal assistance agreement; and (2) If any funds other than Federal appropriated funds have been 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 any application to FTA for Federal assistance, the Applicant assures that it will complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," including the information required by the form's instructions, which may be amended to omit such information as permitted by 31 U.S.C. 1352.

B. The Applicant understands that this certification is a material representation of fact upon which reliance is placed and that submission of this certification is a prerequisite for providing Federal assistance for a transaction covered by 31 U.S.C. 1352. The Applicant also understands that any person who fails to file a required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

III. EFFECTS ON PRIVATE MASS TRANSPORTATION COMPANIES

An Applicant that is a state or local government seeking Federal assistance under 49 U.S.C. chapter 53 to acquire property or an interest in property of a private mass transportation company or operate mass transportation equipment or a facility in competition with or in addition to transportation service provided by an existing mass transportation company must provide the following certification. FTA may not award that Federal assistance until the Applicant provides this certification by selecting Category III on the Signature Page.

As required by 49 U.S.C. 5323(a)(1)(B) or 5323(a)(1)(C), the Applicant certifies that before it acquires property or an interest in property of a private mass transportation company or operates mass transportation equipment or a facility in competition with or in addition to transportation service provided by an existing mass transportation company it has or will have:

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A. Provided for the participation of private mass transportation companies to the maximum extent feasible; and
B. Paid or will pay just compensation under state or local law to a private mass transportation company for its franchises or property acquired.

IV. PUBLIC HEARING CERTIFICATION REQUIRED FOR EACH PROJECT (EXCEPT URBANIZED AREA FORMULA PROJECTS) THAT WILL SUBSTANTIALLY AFFECT A COMMUNITY OR ITS TRANSIT SERVICE

An Applicant for Capital Program assistance or other Federal assistance (except Urbanized Area Formula Program assistance), that will substantially affect a community or its transit service must provide the following certification. FTA may not award that Federal assistance until the Applicant provides this certification by selecting Category IV on the Signature Page.

As required by 49 U.S.C. 5323(b), the Applicant certifies that it has, or before submitting its application, will have:
A. Provided an adequate opportunity for a public hearing with adequate prior notice of the proposed project published in a newspaper of general circulation in the geographic area to be served;
B. Held that hearing and provided FTA a transcript or detailed report summarizing the issues and responses, unless no one with a significant economic, social, or environmental interest requests a hearing;
C. Considered the economic, social, and environmental effects of the project; and
D. Determined the project to be consistent with official plans for developing the urban area.

V. CERTIFICATION OF PRE-AWARD AND POST-DELIVERY ROLLING STOCK REVIEWS REQUIRED FOR EACH APPLICANT SEEKING TO PURCHASE ROLLING STOCK FINANCED WITH FEDERAL ASSISTANCE AWARDED BY FTA

An Applicant seeking FTA assistance to purchase rolling stock must make the following certification. FTA may not provide assistance for any rolling stock acquisition until the Applicant provides this certification by selecting Category V on the Signature Page.

As required by 49 U.S.C. 5323(l), and implementing FTA regulations at 49 CFR 663.7, the Applicant certifies that it will comply with the requirements of 49 CFR part 663, in the course of purchasing revenue service rolling stock. Among other things, the Applicant will conduct or cause to be conducted the prescribed pre-award and post-delivery reviews, and will maintain on file the certifications required by 49 CFR part 663, subparts B, C, and D.

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VI. BUS TESTING CERTIFICATION REQUIRED FOR NEW BUSES

An Applicant seeking FTA assistance to acquire new buses must make the following certification. FTA may not provide assistance for the acquisition of new buses until the Applicant provides this certification by selecting Category VI on the Signature Page.

As required by FTA regulations, "Bus Testing," at 49 CFR 665.7, the Applicant certifies that before expending any Federal assistance to acquire the first bus of any new bus model or any bus model with a new major change in configuration or components or authorizing final acceptance of that bus (as described in 49 CFR part 665):

A. The model of the bus will have been tested at a bus testing facility approved by FTA; and

B. It will have received a copy of the test report prepared on the bus model.

VII. CHARTER SERVICE AGREEMENT

An Applicant seeking FTA assistance to acquire or operate transportation equipment or facilities acquired with Federal assistance authorized by 49 U.S.C. chapter 53 (except 49 U.S.C. 5310) or Title 23, U.S.C. must enter into the following charter service agreement. FTA may not provide assistance for those projects until the Applicant enters into this agreement by selecting Category VII on the Signature Page.

A. As required by 49 U.S.C. 5323(d) and FTA regulations, "Charter Service," at 49 CFR 604.7, the Applicant agrees that it and its recipients will: (1) provide charter service that uses equipment or facilities acquired with Federal assistance authorized for 49 U.S.C. 5307, 5309, or 5311 or Title 23 U.S.C., only to the extent that there are no private charter service operators willing and able to provide the charter service that it or its recipients desire to provide, unless one or more of the exceptions in 49 CFR 604.9 applies, and (2) comply with the provisions of 49 CFR part 604 before they provide any charter service using equipment or facilities acquired with Federal assistance authorized for the above statutes.

B. The Applicant understands that the requirements of 49 CFR part 604 will apply to any charter service provided, the definitions in 49 CFR part 604 apply to this agreement, and violation of this agreement may require corrective measures and the imposition of penalties, including debarment from the receipt of further Federal assistance for transportation.

VIII. SCHOOL TRANSPORTATION AGREEMENT

An Applicant seeking FTA assistance to acquire or operate transportation facilities and equipment acquired with Federal assistance authorized by 49 U.S.C. chapter 53 must agree as follows. FTA may not provide assistance for transportation facilities until the Applicant enters into this Agreement by selecting Category VIII on the Signature Page.

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A. As required by 49 U.S.C. 5323(f) and FTA regulations, "School Bus Operations," at 49 CFR 605.14, the Applicant agrees that it and all its recipients will: (1) engage in school transportation operations in competition with private school transportation operators only to the extent permitted by an exception provided by 49 U.S.C. 5323(f), and implementing regulations, and (2) comply with the requirements of 49 CFR part 605 before providing any school transportation using equipment or facilities acquired with Federal assistance authorized by 49 U.S.C. chapter 53 or Title 23 U.S.C. awarded by FTA for transportation projects.
B. The Applicant understands that the requirements of 49 CFR part 605 will apply to any school transportation it provides, the definitions of 49 CFR part 605 apply to this school transportation agreement, and a violation of this agreement may require corrective measures and the imposition of penalties, including debarment from the receipt of further Federal assistance for transportation.

IX. CERTIFICATION REQUIRED FOR THE DIRECT AWARD OF FTA ASSISTANCE TO AN APPLICANT FOR ITS DEMAND RESPONSIVE SERVICE

An Applicant seeking Federal assistance uirectly to support its demand responsive service must provide the following certification. FTA may not award Federal assistance directly to an Applicant to support its demand responsive service until the Applicant provides this certification by selecting Category IX on the Signature Page.

As required by U.S. DOT regulations, "Transportation Services for Individuals with Disabilities (ADA)," at 49 CFR 37.77, the Applicant certifies that its demand responsive service offered to persons with disabilities, including persons who use wheelchairs, is equivalent to the level and quality of service offered to persons without disabilities. When viewed in its entirety, its service for persons with disabilities is provided in the most integrated setting feasible and is equivalent with respect to: (1) response time, (2) fares, (3) geographic service area, (4) hours and days of service, (5) restrictions on trip purpose, (6) availability of information and reservation capability, and (7) constraints on capacity or service availability.

X. SUBSTANCE ABUSE CERTIFICATIONS

If the Applicant is required by Federal regulations to provide the following substance abuse certifications, FTA may not provide Federal assistance until the Applicant has selected Category X on the Signature Page.

A. Alcohol Testing Certification

As required by FTA regulations, "Prevention of Alcohol Misuse in Transit Operations," at 49 CFR 654.83, the Applicant certifies that it has established and implemented an alcohol misuse prevention program complying with the requirements of 49 CFR part 654; and if the Applicant has employees regulated by the Federal Railroad Administration (FRA), the Applicant also

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certifies that it has for those employees an alcohol misuse prevention program complying with the requirements of FRA's regulations, "Control of Alcohol and Drug Use," 49 CFR part 219.

B. Anti-Drug Program Certification

As required by FTA regulations, "Prevention of Prohibited Drug Use in Transit Operations," at 49 CFR 653.83, the Applicant certifies that it has established and implemented an anti-drug program and has conducted employee training complying with the requirements of 49 CFR part 653; and if the Applicant has employees regulated by the Federal Railroad Administration (FRA), the Applicant also certifies that it has for those employees an anti-drug program complying with the requirements of FRA's regulations, "Control of Alcohol and Drug Use," 49 CFR part 219.

XI. ASSURANCES REQUIRED FOR PROJECTS INVOLVING REAL PROPERTY

The Applicant must provide the following assurances in connection with each application for Federal assistance to acquire (purchase or lease) real property. FTA may not award Federal assistance for a project involving real property until the Applicant provides these assurances shown by selecting Category XI on the Signature Page.

A. Relocation and Real Property Acquisition Assurance

As required by U.S. DOT regulations, "Uniform Relocation Assistance and Real Property Acquisition for Federal and Federally Assisted Programs," at 49 CFR 24.4, and sections 210 and 305 of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended (Uniform Relocation Act), 42 U.S.C. 4630 and 4655, the Applicant assures that it has the requisite authority under applicable state and local law and will comply with the requirements of the Uniform Relocation Act, 42 U.S.C. 4601 et seq., and U.S. DOT regulations, "Uniform Relocation Assistance and Real Property Acquisition for Federal and Federally Assisted Programs," 49 CFR part 24 including, but not limited to the following:
(1) The Applicant will adequately inform each affected person of the benefits, policies, and procedures provided for in 49 CFR part 24;
(2) The Applicant will provide fair and reasonable relocation payments and assistance required by 42 U.S.C. 4622, 4623, and 4624; 49 CFR part 24; and any applicable FTA procedures, to or for families, individuals, partnerships, corporations or associations displaced as a result of any project financed with FTA assistance;
(3) The Applicant will provide relocation assistance programs offering the services described in 42 U.S.C. 4625 to such displaced families, individuals, partnerships, corporations or associations in the manner provided in 49 CFR part 24 and FTA procedures;
(4) Within a reasonable time before displacement, the Applicant will make available comparable replacement dwellings to displaced families and individuals as required by 42 U.S.C. 4625(c)(3);
(5) The Applicant will carry out the relocation process in such a manner as to provide displaced persons with uniform and consistent services, and will make available replacement housing in the

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same range of choices with respect to such housing to all displaced persons regardless of race, color, religion, or national origin; and
(6) In acquiring real property, the Applicant will be guided to the greatest extent practicable under state law, by the real property acquisition policies of 42 U.S.C. 4651 and 4652;
(7) The Applicant will pay or reimburse property owners for necessary expenses as specified in 42 U.S.C. 4653 and 4654, understanding that FTA will participate in the Applicant's costs of providing those payments and that assistance for the project as required by 42 U.S.C. 4631;
(8) The Applicant will execute such amendments to third party contracts and subagreements financed with FTA assistance and execute, furnish, and be bound by such additional documents as FTA may determine necessary to effectuate or implement the assurances provided herein; and
(9) The Applicant agrees to make these assurances part of or incorporate them by reference into any third party contract or subagreement, or any amendments thereto, relating to any project financed by FTA involving relocation or land acquisition and provide in any affected document that these relocation and land acquisition provisions shall supersede any conflicting provisions.

B. Flood Insurance Coverage

As required by section 102(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4012a(a), the Applicant assures that in the course of implementing each project financed with Federal assistance, the Applicant will obtain appropriate insurance for any real estate acquired or construction undertaken thereon within any special flood hazard area as identified by the Federal Insurance Administrator. The Applicant understands that such insurance is available in the participating area through the U.S. Federal Emergency Management Agency's National Flood Insurance Program.

C. Seismic Assurance

As required by U.S. DOT regulations, "Seismic Safety," 49 CFR 41.117(d), the Applicant assures that before it accepts delivery of any building financed with Federal assistance provided by FTA, the Applicant will obtain a certificate of compliance with the seismic design and construction requirements of 49 CFR part 41.

XII. CERTIFICATIONS REQUIRED FOR THE URBANIZED AREA FORMULA PROGRAM

Each Applicant to FTA for Urbanized Area Formula Program assistance authorized for 49 U.S.C. 5307 must provide the following certifications in connection with its application. FTA may not award Urbanized Area Formula Program assistance to the Applicant until the Applicant provides these certifications and assurances shown by selecting Category XII on the Signature Page.

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A. Certifications Required by Statute

As required by 49 U.S.C. 5307(d)(1)(A) through (J), the Applicant certifies that:
(1) It has or will have the legal, financial, and technical capacity to carry out the proposed program of projects;
(2) It has or will have satisfactory continuing control over the use of the equipment and facilities;
(3) It will adequately maintain the equipment and facilities;
(4) It will ensure that the elderly and handicapped persons, or any person presenting a Medicare card issued to himself or herself under title II or title XVIII of the Social Security Act (42 U.S.C. 401 et seq. or 42 U.S.C. 1395 et seq.), will be charged during non-peak hours for transportation using or involving a facility or equipment of a project financed with Federal assistance authorized for 49 U.S.C. 5307 not more than 50 percent of the peak hour fare;
(5) In carrying out a procurement financed with Federal assistance authorized for the Urbanized Area Formula Program at 49 U.S.C. 5307, it will use competitive procurement (as defined or approved by the Secretary), it will not use a procurement using exclusionary or discriminatory specifications, and it will comply with applicable Buy America laws in carrying out a procurement;
(6) It has complied or will comply with the requirements of 49 U.S.C. 5307(c); specifically, it has or before submitting its application it will: (a) make available to the public information on amounts available for the Urbanized Area Formula Program at 49 U.S.C. 5307 and the program of projects it proposes to undertake with those funds; (b) develop, in consultation with interested parties, including private transportation providers, a proposed program of projects for activities to be financed; (c) publish a proposed program of projects in a way that affected citizens, private transportation providers, and local elected officials have the opportunity to examine the proposed program and submit comments on the proposed program and the performance of the Applicant; (d) provide an opportunity for a public hearing to obtain the views of citizens on the proposed program of projects; and (e) ensure that the proposed program of projects provides for the coordination of transportation services assisted under 49 U.S.C. 5336 with transportation services assisted by another Federal Government source; (f) consider comments and views received, especially those of private transportation providers, in preparing the final program of projects; and (g) make the final program of projects available to the public;
(7) It has or will have available and will provide the amount of funds required by 49 U.S.C. 5307(e) and applicable FTA policy (specifying Federal and local shares of project costs);
(8) It will comply with: (a) 49 U.S.C. 5301(a) (requirements to develop transportation systems that maximize mobility and minimize fuel consumption and air pollution); (b) 49 U.S.C. 5301(d) (requirements for transportation of the elderly and persons with disabilities); (c) 49 U.S.C. 5303 through 5306 (planning requirements); and (d) 49 U.S.C. 5310(a) through (d) (programs for the elderly and persons with disabilities);
(9) It has a locally developed process to solicit and consider public comment before raising fares or implementing a major reduction of transportation; and
(10) As required by 49 U.S.C. 5307(d)(1)(J), it will expend at least one percent of the amount of Federal assistance it receives for this fiscal year apportioned by 49 U.S.C. 5336 for transit security projects, including increased lighting in or adjacent to a transit system (including bus stops, subway stations, parking lots, and garages), increased camera surveillance of an area in or adjacent to that system, emergency telephone line or lines to contact law enforcement or security

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personnel in an area in or adjacent to that system, and any other project intended to increase the security and safety of an existing or planned transit system; unless it has decided that it is not necessary to expend one percent of that Federal assistance this fiscal year for transit security projects.

B. Certification Required for Capital Leasing

As required by FTA regulations, "Capital Leases," 49 CFR at 639.15(b)(1) and 639.21, to the

extent that the Applicant uses Federal assistance authorized for 49 U.S.C. 5307 to acquire any capital asset by lease, the Applicant certifies that:
(1) It will not use Federal assistance authorized for 49 U.S.C. 5307 to finance the cost of leasing any capital asset until it undertakes calculations demonstrating that it is more cost-effective to lease the capital asset than to purchase or construct similar assets;
(2) It will complete these calculations before entering into the lease or before receiving a capital grant for the asset, whichever is later; and
(3) It will not enter into a capital lease for which FTA can only provide incremental funding unless it has the financial capacity to meet its future obligations under the lease in the event Federal assistance is not available for capital projects in subsequent years.

C. Certification Required for Sole Source Purchase of Associated Capital Maintenance Item

As required by 49 U.S.C. 5325(c), to the extent that the Applicant procures an associated capital maintenance item under the authority of 49 U.S.C. 5307(b)(1), the Applicant certifies that it will use competition to procure an associated capital maintenance item unless the manufacturer or supplier of that item is the only source for the item and the price of the item is no more than the price similar customers pay for the item, and maintain sufficient records pertaining to each such procurement on file easily retrievable for FTA inspection.

XIII. CERTIFICATIONS AND ASSURANCES FOR THE ELDERLY AND PERSONS WITH DISABILITIES PROGRAM

An Applicant that intends to administer, on behalf of the state, the Elderly and Persons with Disabilities Program must provide the following certifications and assurances. FTA may not award assistance for the Elderly and Persons with Disabilities Program until the Applicant provides these certifications and assurances by selecting Category XIII on the Signature Page.

Based on its own knowledge and, as necessary, on information submitted by the subrecipient, the Applicant administering on behalf of the state the Elderly and Persons with Disabilities Program authorized by 49 U.S.C. 5310 certifies and assures that the following requirements and conditions will be fulfilled:

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A. The state organization serving as the Applicant and each subrecipient has or will have the necessary legal, financial, and managerial capability to apply for, receive, and disburse Federal assistance authorized for 49 U.S.C. 5310; and to implement and manage the project.

B. The state assures that each subrecipient either is recognized under state law as a private nonprofit organization with the legal capability to contract with the state to carry out the proposed project, or is a public body that has met the statutory requirements to receive Federal assistance authorized for 49 U.S.C. 5310.

C. The subrecipient's application for 49 U.S.C. 5310 assistance contains information from which the state concludes that the transit service provided or offered to be provided by existing public or private transit operators is unavailable, insufficient, or inappropriate to meet the special needs of the elderly and persons with disabilities.

D. The state assures that sufficient non-Federal funds have been or will be committed to provide the required local share.

E. The subrecipient has, or will have by the time of delivery, sufficient funds to operate and maintain the vehicles and equipment purchased with Federal assistance awarded for this project.

F. The state assures that before issuing the state's formal approval of a project, its Elderly and Persons with Disabilities Formula Program is included in the Statewide Transportation Improvement Program as required by 23 U.S.C. 135; all projects in urbanized areas recommended for approval are included in the annual element of the metropolitan Transportation Improvement Program in which the subrecipient is located; and it has obtained from any public body that is a prospective subrecipient of capital assistance a certification that an opportunity for a public hearing has been provided.

G. The subrecipient has, to the maximum extent feasible, coordinated with other transportation providers and users, including social service agencies authorized to purchase transit service.

H. The subrecipient is in compliance with all applicable civil rights requirements, and has signed the Nondiscrimination Assurance. (Category I.F., "Certifications and Assurances Required of Each Applicant.")

I. The subrecipient will comply with applicable requirements of U.S. DOT regulations on participation of disadvantaged business enterprises in U.S. DOT programs.

J. The state will comply with all existing Federal requirements regarding transportation of elderly persons and persons with disabilities. The subrecipient has provided to the state an Assurance of Nondiscrimination on the Basis of Disability, as set forth in the Certifications and Assurances required of each Applicant for FTA assistance. (Category I.G., "Certifications and Assurances Required of Each Applicant.") If non-accessible vehicles are being purchased for use by a public entity in demand responsive service for the general public, the state will obtain from the subrecipient a "Certification of Equivalent Service," which states that the public entity's demand responsive service offered to persons with disabilities, including persons who use wheelchairs, is equivalent to the level and quality of service the public entity offers to persons without disabilities. (See Category IX, "Certifications Required for the Direct Award of FTA Assistance to an Applicant for its Demand Responsive Service.") This "Certification of Equivalent Service" must also state that the public entity's demand responsive service, when viewed in its entirety, is provided in the most integrated setting feasible and has equivalent: (1) response time, (2) fares, (3) geographic service area, (4) hours and days of service, (5) restrictions or restraints on trip

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purpose, (6) availability of information and reservation capability, and (7) constraints on capacity or service availability.

K. The subrecipient has certified to the state that it will comply with applicable provisions of 49 CFR part 605 pertaining to school transportation operations. (See Category VIII, "School Transportation Agreement.")

L. Unless otherwise noted, each of the subrecipient's projects qualifies for a categorical exclusion and does not require further environmental approvals, as described in the joint FHWA/FTA regulations, "Environmental Impact and Related Procedures," at 23 CFR 771.117(c). The state certifies that financial assistance will not be provided for any project that does not qualify for a categorical exclusion described in 23 CFR 771.117(c) until FTA has made the required environmental finding. The state further certifies that no financial assistance will be provided for a project requiring a conformity finding in accordance with the Environmental Protection Agency's Clean Air Conformity regulations at 40 CFR parts 51 and 93, until FTA makes the required conformity finding.

M. The subrecipient has submitted (or will submit) all certifications and assurances currently required, including, but not limited to: a certification that its procurements and procurement system will comply with all applicable requirements imposed by Federal laws, executive orders, or regulations and the requirements of FTA Circular 4220.1D, "Third Party Contracting Requirements," and other implementing requirements FTA may issue; a certification that its project provides for the participation of private mass transportation companies to the maximum extent feasible; a certification it has paid or will pay just compensation under state or local law to each private mass transportation company for its franchise or property acquired under the project; a nonprocurement suspension and debarment certification; a bus testing certification for new models; a pre-award and post-delivery review certification; and a lobbying certification for each application exceeding $100,000. Certifications and assurances applicable to and submitted by the subrecipient should be substantially similar to the text of parallel certifications and assurances text of Categories I-XI of this document, but modified as necessary to accommodate the subrecipient's circumstances.

N. The state will enter into a written agreement with each subrecipient stating the terms and conditions of assistance by which the project will be undertaken and completed.

O. The state recognizes FTA's authority to conduct audits to verify compliance with the foregoing requirements and stipulations.

XIV. CERTIFICATIONS AND ASSURANCES FOR THE NONURBANIZED AREA FORMULA PROGRAM

An Applicant that intends to administer, on behalf of the state, the Nonurbanized Area Formula Program must provide the following certifications and assurances. FTA may not award Nonurbanized Area Formula Program assistance to the Applicant until the Applicant provides these certifications and assurances shown by selecting Category XIV on the Signature Page.

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Based on its own knowledge and, as necessary, on information submitted by the subrecipient, the Applicant administering on behalf of the state the Nonurbanized Area Formula Program authorized by 49 U.S.C. 5311 certifies and assures that the following requirements and conditions will be fulfilled:

A. The state organization serving as the Applicant and each subrecipient has or will have the necessary legal, financial, and managerial capability to apply for, receive and disburse Federal assistance authorized for 49 U.S.C. 5311; and to implement and manage the project.

B. The state assures that sufficient non-Federal funds have been or will be committed to provide the required local share.

C. The subrecipient has, or will have by the time of delivery, sufficient funds to operate and maintain the vehicles and equipment purchased with Federal assistance authorized for this project.

D. The state assures that before issuing the state's formal approval of the project, its Nonurbanized Area Formula Program is included in the Statewide Transportation Improvement Program as required by 23 U.S.C. 135; to the extent applicable, projects are included in a metropolitan Transportation Improvement Program, and it has obtained from the prospective subrecipient of capital assistance a certification that an opportunity for a public hearing has been provided.

E. The state has provided for a fair and equitable distribution of Federal assistance authorized for 49 U.S.C. 5311 within the state, including Indian reservations within the state.

F. The subrecipient has, to the maximum extent feasible, coordinated with other transportation providers and users, including social service agencies authorized to purchase transit service.

G. The subrecipient is in compliance with all applicable civil rights requirements, and has signed the Nondiscrimination Assurance. (See Category I.F, "Certifications and Assurances Required of Each Applicant.")

H. The subrecipient will comply with applicable requirements of U.S. DOT regulations on participation of disadvantaged business enterprise in U.S. DOT programs.

I. The state will comply with all existing Federal requirements regarding transportation of elderly persons and persons with disabilities. The subrecipient has provided to the state an Assurance of Nondiscrimination on the Basis of Disability, as set forth in the Certifications and Assurances required of each Applicant for FTA assistance in Category I of this document. If non-accessible vehicles are being purchased for use by a public entity in demand responsive service for the general public, the state will obtain from the subrecipient a "Certification of Equivalent Service," which states that the public entity's demand responsive service offered to persons with disabilities, including persons who use wheelchairs, is equivalent to the level and quality of service the public entity offers to persons without disabilities. (See Category I.G, "Certifications and Assurances Required of Each Applicant.") This "Certification of Equivalent Service" must also state that the public entity's demand responsive service, when viewed in its entirety, is provided in the most integrated setting feasible and has equivalent: (1) response time, (2) fares, (3) geographic service area, (4) hours and days of service, (5) restrictions and restraints on trip purpose, (6) availability of information and reservation capability, and (7) constraints on capacity or service availability. (See Category IX, "Certifications Required for the Direct Award of FTA Assistance to an Applicant for its Demand Responsive Service.")

J. The subrecipient has complied with the transit employee protective provisions of 49 U.S.C. 5333(b), by one of the following actions: (1) signing the Special Warranty for the Nonurbanized

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Area Formula Program, (2) agreeing to alternative comparable arrangements approved by the Department of Labor (DOL), or (3) obtaining a waiver from DOL; and the state has certified the subrecipient's compliance to DOL.

K. The subrecipient has certified to the state that it will comply with 49 CFR part 604 in the provision of any charter service provided with equipment or facilities acquired with FTA assistance, and will also comply with applicable provisions of 49 CFR part 605 pertaining to school transportation operations. (See Category VII, "Charter Service Agreement," and Category VIII, "School Transportation Agreement.")

L. Unless otherwise noted, each of the subrecipient's projects qualifies for a categorical exclusion and does not require further environmental approvals, as described in the joint FHWA/FTA regulations, "Environmental Impact and Related Procedures," at 23 CFR 771.117(c). The state certifies that financial assistance will not be provided for any project that does not qualify for a categorical exclusion described in 23 CFR 771.117(c) until FTA has made the required environmental finding. The state further certifies that no financial assistance will be provided for a project requiring a conformity finding in accordance with the Environmental Protection Agency's Clean Air Conformity regulations at 40 CFR parts 51 and 93, until FTA makes the required conformity finding.

M. The subrecipient has submitted (or will submit) all certifications and assurances currently required, including but not limited to: a certification that its procurements and procurement system will comply with all applicable requirements imposed by Federal laws, executive orders, or regulations and the requirements of FTA Circular 4220.1D, "Third Party Contracting Requirements," and other implementing requirements FTA may issue, a certification that its project provides for the participation of private mass transportation companies to the maximum extent feasible; a certification it has paid or will pay just compensation under state or local law to each private mass transportation company for its franchise or property acquired under the project; a nonprocurement suspension and debarment certification; a bus testing certification for new bus models; a pre-award and post-delivery review certification; a lobbying certification for each application exceeding $100,000; and if required by FTA, an anti-drug program certification and an alcohol testing certification. Certifications and assurances applicable to and submitted by the subrecipient should be substantially similar to the text of parallel certifications and assurances text of Categories I-XI of this document, but modified as necessary to accommodate the subrecipient's circumstances.

N. The state will enter into a written agreement with each subrecipient stating the terms and conditions of assistance by which the project will be undertaken and completed.

O. The state recognizes FTA's authority to conduct audits to verify compliance with the foregoing requirements and stipulations.

P. As required by 49 U.S.C. 5311(f), it will expend not less than fifteen percent of the Federal assistance authorized for 49 U.S.C. 5311(f) it receives during this fiscal year to carry out a program to develop and support intercity bus transportation, unless the chief executive officer of the state or his or her duly authorized designee certifies that the intercity bus service needs of the state are being adequately met.

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XV. CERTIFICATIONS AND ASSURANCES FOR THE STATE INFRASTRUCTURE BANK PROGRAM

A state Applicant for a grant of Federal assistance for deposit in the Transit Account of the State Infrastructure Bank (SIB) within that state must provide the following certifications and assurances. The Federal Transit Administration (FTA) may not award Federal assistance to capitalize a SIB until the state Applicant provides these certifications and assurances.

Based on its own knowledge and, as necessary, on requisite information submitted by the participating parties, the state Applicant for Federal assistance for the Transit Account of its state SIB program, authorized by section 350 of the National Highway System Designation Act of 1995 (NHS Act), as amended, 23 U.S.C. 101 note, certifies and assures that the following requirements and conditions will be fulfilled pertaining to any project financed with Federal assistance derived from the Transit Account of the SIB:

A. The state organization serving as the Applicant (state) agrees and assures the agreement of the SIB and each recipient of Federal assistance derived from the Transit Account of the SIB within the state (subrecipient) that each Project financed with Federal assistance derived from the Transit Account will be administered in accordance with: (1) the requirements of section 350 of the National Highway System Designation Act of 1995 (NHS Act), Pub. L. 104-59, Nov. 28, 1995, 23 U.S.C. 101 note, (2) the provisions of FTA's NHS Guidelines, and any amendments thereto, (3) the provisions of FHWA and FTA Cooperative Agreement with the state to establish the state's SIB program, and (4) the provisions of the FTA Grant Agreement with the state obligating Federal assistance for the Transit Account of the SIB, except that any provision of the Federal Transit Administration Master Agreement incorporated by reference into that Grant Agreement that conflicts with any provision of FTA's NHS Guidelines, the provisions of the Cooperative Agreement establishing the SIB program within the state, or the text within the Grant Agreement will not apply.

B. The state agrees to comply with and assures the compliance of the SIB and each subrecipient of all applicable requirements for the SIB program, as those requirements may be amended from time to time.

C. The state assures that the SIB will provide Federal assistance from its Transit Account only for transit capital projects eligible under section 350 of the NHS Act, and that those projects will fulfill all requirements imposed on comparable capital transit projects financed by FTA.

D. The state understands that the total amount of funds to be awarded for a Grant Agreement will not be immediately available for draw down. Consequently, the state assures that it will limit the amount of Federal assistance it draws down for deposit in the Transit Account of its SIB to amounts that do not exceed the limitations specified in the underlying Grant Agreement or the Approved Project Budget for that Grant Agreement.

E. The state assures that each subrecipient has or will have the necessary legal, financial, and managerial capability to apply for, receive, and disburse Federal assistance authorized by Federal statute for use in the Transit Account of the SIB, and to implement, manage, operate, and maintain the project and project property for which such assistance will support.

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F. The state assures that the SIB will provide Federal assistance derived from the Transit Account only to a subrecipient that is either a public or private entity recognized under state law as having the legal capability to contract with the state to carry out its proposed project.
G. The state assures that sufficient non-Federal funds have been or will be committed to provide the required local share.
H. The state assures that the SIB will enter into a written agreement with each subrecipient stating the terms and conditions of assistance by which the project will be undertaken and completed, including specific provisions that any security or debt financing instrument the SIB may issue will contain an express statement that the security or instrument does not constitute a commitment, guarantee, or obligation of the United States.
I. The state assures that before the SIB enters into an agreement with a subrecipient under which Federal assistance within the Transit Account of the SIB will be disbursed to the subrecipient, the subrecipient's project is included in the Statewide Transportation Improvement Program; all projects in urbanized areas recommended for approval are included in the annual element of the metropolitan Transportation Improvement Program in which the subrecipient is located; and it has obtained from each subrecipient of capital assistance that is also a public body a certification that an opportunity for a public hearing has been provided.
J. The state assures that the subrecipient has, to the maximum extent feasible, coordinated with other transportation providers and users, and other interested parties within the area.
K. The state assures that the subrecipient is in compliance with all applicable civil rights requirements, and has signed the Nondiscrimination Assurance. (See Category I.F, "Certifications and Assurances Required of Each Applicant," of the Federal Fiscal Year 1997 Certifications and Assurances for the Federal Transit Administration Programs.)
L. The state assures that the subrecipient will comply with applicable requirements of U.S. DOT regulations on participation of disadvantaged business enterprises in U.S. DOT programs.
M. To the extent applicable, the state will comply with all existing Federal requirements regarding transportation of elderly persons and persons with disabilities. The state assures that the SIB will provide to the state an Assurance of Nondiscrimination on the Basis of Disability from each subrecipient, as set forth in the Certifications and Assurances required of each Applicant for FTA assistance. (See Category I.G, "Certifications and Assurances Required of Each Applicant," of the Federal Fiscal Year 1997 Certifications and Assurances for the Federal Transit Administration Programs.) If non-accessible vehicles are being purchased for use by a public entity in demand responsive service for the general public, the state will obtain from the subrecipient a "Certification of Equivalent Service," which states that the public entity's demand responsive service offered to persons with disabilities, including persons who use wheelchairs, is equivalent to the level and quality of service the public entity offers to persons without disabilities. (See Category IX, "Certifications Required for the Direct Award of FTA Assistance to an Applicant for its Demand Responsive Service," of the Federal Fiscal Year 1997 Certifications and Assurances for the Federal Transit Administration Programs.) This "Certification of Equivalent Service" must also state that the public entity's demand responsive service, when viewed in its entirety, is provided in the most integrated setting feasible and has equivalent: (1) response time, (2) fares, (3) geographic service area, (4) hours and days of service, (5) restrictions or restraints on trip purpose, (6) availability of information and reservation capability, and (7) constraints on capacity or service availability.

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N. The state assures that before the SIB provides Federal assistance from the Transit Account, each subrecipient will have complied with the applicable transit employee protective provisions of 49 U.S.C. 5333(b) as required for that subrecipient and its project.

O. The state assures that each subrecipient has certified or will certify to the state that it will comply with 49 CFR part 604 in the provision of any charter service provided with equipment or facilities acquired with FTA assistance, and will also comply with applicable provisions of 49 CFR part 605 pertaining to school transportation operations. (See Category VII, "Charter Service Agreement," and Category VIII, "School Transportation Agreement," of the Federal Fiscal Year 1997 Certifications and Assurances for the Federal Transit Administration Programs.)

P. Unless otherwise noted, the state assures that each of the subrecipient's projects qualifies for a categorical exclusion and does not require further environmental approvals, as described in Q. Unless otherwise noted, the state assures that each of the subrecipient's projects qualifies for a categorical exclusion and does not require further environmental approvals, as described in the joint FHWA/FTA regulations, "Environmental Impact and Related Procedures," at 23 CFR 771.117(c). The state certifies that the SIB will not provide financial assistance from the Transit Account for any project that does not qualify for a categorical exclusion described in 23 CFR 771.117(c) until FTA has made the required environmental finding. The state further certifies that the SIB will provide no financial assistance from its Transit Account for a project requiring a conformity finding in accordance with the Environmental Protection Agency's Clean Air Conformity regulations at 40 CFR parts 51 and 93, until FTA makes the required conformity finding.

Q. The state assures that the subrecipient has submitted (or will submit), when applicable, all certifications and assurances currently required, including, but not limited to: a certification that its procurements and procurement system will comply with all applicable requirements imposed by Federal laws, executive orders, or regulations and the requirements of FTA Circular 4220.1D, "Third Party Contracting Requirements," and other implementing requirements FTA may issue; a certification that its project provides for the participation of private mass transportation companies to the maximum extent feasible; a certification it has paid or will pay just compensation under state or local law to each private mass transportation company for its franchise or property acquired under the project; a nonprocurement suspension and debarment certification; a bus testing certification for new models; a pre-award and post-delivery review certification; and a lobbying certification for each application exceeding $100,000; assurances FTA requires for projects involving real property; and if required by FTA, an anti-drug program certification and an alcohol testing certification. Certifications and assurances applicable to and submitted by the subrecipient should be substantially similar to the text of parallel certifications and assurances of Categories I-XI of the Federal Fiscal Year 1997 Certifications and Assurances for the Federal Transit Administration Programs, but modified as necessary to accommodate the SIB and the subrecipient's circumstances.

R. The state agrees and assures that the SIB and each subrecipient will agree to permit FTA, U.S. DOT, and the Comptroller General to conduct audits to verify compliance with the foregoing requirements and stipulations.

##

Selection and Signature Pages follow.

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FEDERAL FY 1997 CERTIFICATIONS AND ASSURANCES FOR FTA ASSISTANCE

Name of Applicant: _____

The Applicant agrees to comply with applicable requirements of Categories I - XV. ____
(The Applicant may make this selection in lieu of individual selections below.)

OR

The Applicant agrees to comply with the applicable requirements of the following categories it has selected:

I. Certifications and Assurances Required of Each Applicant. ____

II. Lobbying Certification. ____

III. Effects on Private Mass Transportation Companies. ____

IV. Public Hearing Certification for Major Projects with Substantial Impacts. ____

V. Certification for the Purchase of Rolling Stock. ____

VI. Bus Testing Certification. ____

VII. Charter Service Agreement. ____

VIII. School Transportation Agreement. ____

IX. Certification for Demand Responsive Service. ____

X. Substance Abuse Certifications. ____

XI. Assurances Projects Involving Real Property. ____

XII. Certifications for the Urbanized Area Formula Program. ____

XIII. Certifications for the Elderly and Persons with Disabilities Program. ____

XIV. Certifications for the Nonurbanized Area Formula Program. ____

XV. Certifications for the State Infrastructure Bank (SIB) Program ____
(Both sides of this Signature Page must be appropriately completed and signed where indicated.)

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FTA CERTIFICATIONS AND ASSURANCES FOR FEDERAL FISCAL YEAR 1997

Name of Applicant: _____

Name and Relationship of Authorized Representative: _____

BY SIGNING BELOW I, _____ (name), on behalf of the Applicant, declare that the Applicant has duly authorized me to make these certifications and assurances and bind the Applicant's compliance. Thus, the Applicant agrees to comply with all Federal statutes, regulations, executive orders, and administrative guidance required for each application it makes to the Federal Transit Administration (FTA) in Federal Fiscal Year 1997.

FTA intends that the certifications and assurances the Applicant selects on the other side of this document, as representative of the certifications and assurances in Appendix A, should apply, as required, to each project for which the Applicant seeks now, or may later, seek FTA assistance during Federal Fiscal Year 1997.

The Applicant affirms the truthfulness and accuracy of the certifications and assurances it has made in the statements submitted herein with this document and any other submission made to FTA, and acknowledges that the provisions of the Program Fraud Civil Remedies Act of 1986, 31 U.S.C. 3801 et seq., as implemented by U.S. DOT regulations, "Program Fraud Civil Remedies," 49 CFR part 31 apply to any certification, assurance or submission made to FTA. The criminal fraud provisions of 18 U.S.C. 1001 apply to any certification, assurance, or submission made in connection with the Urbanized Area Formula Program, 49 U.S.C. 5307, and may apply to any other certification, assurance, or submission made in connection with any other program administered by FTA.

In signing this document, I declare under penalties of perjury that the foregoing certifications and assurances, and any other statements made by me on behalf of the Applicant are true and correct.

Date: _____ a. _____
Authorized Representative of Applicant

AFFIRMATION OF APPLICANT'S ATTORNEY

for _____ (Name of Applicant)

As the undersigned legal counsel for the above named Applicant, I hereby affirm that the Applicant has authority under state and local law to make and comply with the certifications and assurances as indicated on the foregoing pages. I further affirm that, in my opinion, the certifications and assurances have been legally made and constitute legal and binding obligations on the Applicant.

I further affirm that, to the best of my knowledge, there is no legislation or litigation pending or imminent that might adversely affect the validity of these certifications and assurances, or of the performance of the project. Furthermore, if I become aware of circumstances that change the accuracy of the foregoing statements, I will notify the Applicant and FTA promptly.

Date: _____ b. _____
Applicant's Attorney

Date: _____ c. _____

Unless the Applicant seeks only an FTA university and research training grant authorized by 49 U.S.C. 5312(b), the Applicant's legal counsel is required to affirm the legal capacity of the Applicant. The Attorney's Affirmation for a previous FTA project is generally valid in Fiscal Year 1997, provided the Applicant's circumstances have not changed in a way that makes the certifications invalid and the Attorney's Affirmations remains on file in the Applicant's offices readily available to FTA. In that case, line "b" should remain blank, and the same Authorized Representative signs "a." and "c." See Procedures in introduction section. Note: FTA, however, reserves the right to require an Attorney's signature on line "b."

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BILLING CODE 4910–57–C

federal register

Monday
October 7, 1996

Part IV

Department of Education

34 CFR Part 222

Office of Elementary and Secondary Education; Impact Aid Program; Proposed Rules

DEPARTMENT OF EDUCATION

34 CFR Part 222

RIN 1810–AA84

Office of Elementary and Secondary Education; Impact Aid Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to issue regulations governing the Impact Aid Program under title VIII of the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the Improving America's Schools Act of 1994 (IASA). The program, in general, provides assistance for maintenance and operations costs to local educational agencies (LEAs) that are affected by Federal activities. These proposed regulations are needed to implement a number of changes from the previous Impact Aid laws, Public Law 81–874 and Public Law 81–815, which were repealed when title VIII of the ESEA was enacted, and clarify and improve the administration of the program.

DATES: Written comments must be received on or before December 6, 1996.

ADDRESSES: All comments concerning the proposed regulations should be addressed to Catherine Schagh, U.S. Department of Education, Impact Aid Program, 600 Independence Avenue, S.W., Room 4200, Portals Building, Washington, DC 20202–6244. The fax number for submitting these comments is (202) 205–0088. Comments may also be sent through the Internet to Catherine__Schagh@ed.gov.

To ensure that public comments have maximum effect in developing the final regulations, the Department urges that each comment clearly identify the specific section or sections of the proposed regulations that the comment addresses and that comments be in the same order as the proposed regulations.

A copy of any comments that concern information collection requirements should also be sent to the Office of Management and Budget at the address listed in the Paperwork Reduction Act section of this preamble.

FOR FURTHER INFORMATION CONTACT: For further information on this part, please contact Catherine Schagh. Telephone: (202) 260–3858. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: On October 20, 1994, the President signed into law the IASA (Pub. L. 103–382). The IASA reauthorized the Impact Aid Program as title VIII of the ESEA, and made a number of changes to the program. Under the Impact Aid Program, assistance is provided for maintenance and operations costs to LEAs affected by Federal activities, including the presence of tax-exempt Federal property and an increased student population due to Federal property ownership or activities.

On March 4, 1995, President Clinton issued a regulatory reinvention initiative directing heads of departments and agencies to review all existing regulations to eliminate those that are outdated and modify others to increase flexibility and reduce burden. The Department has undertaken a thorough review of the existing Impact Aid Program regulations in light of this initiative. In addition, Department staff have met on numerous occasions with Impact Aid applicants and other interested parties at National Association for Federally Impacted Schools meetings to converse and solicit views about possible changes to the current regulations due both to statutory changes and burden reduction.

As a part of that process, the Secretary published in the Federal Register on September 29, 1995, a final regulation removing regulations that were obsolete due to changes made in the statute by the IASA, or that were unnecessary because they simply repeated statutory provisions. In addition, in that regulation, the Secretary reorganized, streamlined, and revised the remaining regulations so that they were more logically organized, clearly stated, and easier to use. Except where changes were necessary to conform the previous regulations to the new Impact Aid law (title VIII of the ESEA), and for a few minor procedural changes, those final regulations contained the same substantive provisions as the previous regulations.

The Secretary indicated in those technical regulations that he intended to publish a notice of proposed rulemaking (NRPM) in the future to implement provisions of the new law that were not included in those final regulations, and to make any substantive changes that were identified as needed under the Secretary's reinvention review. The Secretary now is publishing this NPRM to accomplish those objectives.

Summary of Provisions

General

In subpart A (general provisions), § 222.4 would be revised to be consistent with the proof of mailing requirements under the Education Department General Administrative Regulations that apply to other Department programs. Under this provision, private metered postmarks or mail receipts that are not dated by the U.S. Postal Service would not be accepted as proof of mailing.

Implementation of New Statutory Provisions

1. *Overpayment forgiveness provision (section 8012 of the ESEA).* New §§ 222.12–222.15 would be added to subpart A to implement the Secretary's new authority in section 8012 of the ESEA to forgive Impact Aid overpayments under certain circumstances. Proposed § 222.12 would specify what overpayments the Secretary considers eligible for forgiveness under section 8012. As described in proposed § 222.12(a)(1), the provision generally would apply to funds received by an LEA in excess of the amount the LEA was eligible to receive under Pub. L. 81–874, Pub. L. 81–815, or title VIII of the ESEA, but only to the extent that a balance is owed on or after the effective date of the final regulations. The provision would apply to a full overpayment under those laws (including any portion of the overpayment that has been repaid) if the overpayment is the subject of a written request for forgiveness filed by the LEA before the effective date of the final regulations, or of a timely written request for an administrative hearing or reconsideration. This is because these requests generally preserve the full overpayment debt pending resolution of the disputed action.

The Secretary would not extend application of this forgiveness provision to the limited portions of the program that require LEAs to expend the Federal funds for specific purposes other than general maintenance and operations (such as for disaster assistance under section 7 of Public Law 81–874 or section 16 of Public Law 81–815, or to provide a free appropriate education for federally connected children with disabilities under section 8003(d) of the ESEA or section 3(d)(2)(C) of Pub. L. 81–874). Unlike most other ESEA programs, Congress has not granted authority in the Impact Aid program statute to the Secretary to grant waivers of certain programmatic requirements, such as for the required use of funds.

Accordingly, proposed § 222.12(a)(2) specifies that the provision would not apply to overpayments under section 7 of Public Law 81–874 or section 16 of Public Law 81–815 (disaster assistance program). This is because these overpayments generally are due either to an LEA's misexpenditure of funds or to its receipt of funds in excess of its actual eligible disaster assistance costs. Likewise, this provision would not apply to overpayments resulting from an LEA's failure to expend or account for funds properly under section 8003(d) of the ESEA (subpart D of the regulations) or its predecessor provision, section 3(d)(2)(C) of Public Law 81–874, for certain federally connected children with disabilities, or under section 8003(g) of the ESEA for certain federally connected children with severe disabilities (subpart F of these proposed regulations).

Proposed § 222.12(a)(2) also specifies that the forgiveness provision would not apply to amounts received by an LEA that, as determined under section 8003(g) of the ESEA (authorizing payments to LEAs for costs associated with certain federally connected children with severe disabilities), were in excess of the maximum basic support payment for which the LEA was eligible under section 8003(b) of the ESEA. Under section 8003(g), if an LEA receives Federal funds for Impact Aid purposes from sources other than the Impact Aid program (*e.g.*, the Department of Defense), and the total of the funds from other sources and the LEA's payment under section 8003(b) exceeds the maximum basic support payment for which the LEA was eligible, the excess amount must be made available for redistribution to LEAs that provide an education to certain federally connected children with severe disabilities.

Proposed § 222.13 sets forth the basic requirements that an LEA must meet for an eligible overpayment to be forgiven in whole or part. Section 222.13(a)(1) provides that the Secretary would forgive an eligible overpayment in whole or part only if an LEA timely files a request for forgiveness and certain information and documentation. In addition, as specified in proposed § 222.13(a)(2), the Secretary must determine in accordance with proposed § 222.14, in the case either of an LEA's or the Department's error, that repayment of the LEA's total eligible overpayments will result in an undue financial hardship on the LEA and seriously harm the LEA's educational program. In the case of Department error, an overpayment also would qualify if the Secretary determined, on a case-by-case basis, that repayment would be manifestly unjust.

Proposed § 222.13(b) specifies the time limits within which an LEA must file its forgiveness request and supporting information and documentation. Under that proposed provision, an LEA generally must file a forgiveness request in writing within 30 days of its initial receipt of a notice of an overpayment. For an overpayment for which an LEA has submitted a written forgiveness request before the effective date of the final regulations, the LEA would be required to file the supporting information and documentation within 30 days from the effective date of the regulations. For all other overpayments, proposed § 222.13(b)(3) specifies that an LEA would be required to provide the specific information and documentation concerning financial hardship within the same time period that applies to the forgiveness request. In either case, the Secretary may grant a written extension of the applicable time period for the submission of the information and documentation due to lack of availability of that data.

Proposed § 222.13(c)(1) specifies the types of information and documentation that an LEA must provide in support of its written forgiveness request. All LEAs would be required to provide the following (as applicable) for the LEA's fiscal year preceding the date of the request: A copy of the LEA's annual financial report to the State; the LEA's local real property tax rate for current expenditure purposes; the maximum local real property tax rate for current expenditure purposes allowed by State law, or if there is no State maximum, the average local real property tax rate of all LEAs in the State; and the LEA's equalized assessed valuation of real property per pupil (EAVPP) (or other measure of fiscal capacity as defined by the State), and the average of that measure for all LEAs in the State. The Secretary believes this is the minimum information necessary to determine an LEA's eligibility for overpayment forgiveness under the standard proposed in § 222.14, and the amount to be forgiven under proposed § 222.15.

For an LEA whose boundaries are the same as a Federal military installation, the LEA also would be required to provide the average per pupil expenditure (PPE) of the LEA, and the average PPE in all LEAs in the State. In addition, proposed § 222.13(c)(2) requires an LEA requesting forgiveness under the manifestly unjust repayment exception (proposed § 222.13(a)(2)(ii)), or based upon no present or prospective ability to repay the debt (proposed § 222.14(a)(2)), to submit additional information and documentation in support of its request for forgiveness under those special provisions.

Proposed § 222.13(d)(1) clarifies that, like a request for reconsideration, a request for forgiveness of an overpayment does not extend the time within which an applicant must file an administrative hearing request under § 222.151, unless the Secretary (or Secretary's delegatee) extends that time limit in writing. Similarly, proposed § 222.13(d)(2) provides that a request for an administrative hearing or for reconsideration does not extend the time within which an applicant must file a request for forgiveness under §§ 222.12–222.15, unless the Secretary (or the Secretary's delegatee) extends that time limit in writing.

Proposed § 222.14 describes how the Secretary will determine whether repayment of an eligible overpayment would result in undue financial hardship and seriously harm the LEA's educational program. It is the Secretary's intent in publishing these regulations to establish a reasonable measure of undue financial hardship that may be objectively applied, and that fairly balances the competing interests of applicants eligible for redistribution of overpaid Impact Aid funds with the interests of those districts applying for forgiveness. Comments and suggestions are invited on whether these proposed regulations achieve that balance and reasonably measure undue financial hardship.

As described in proposed § 222.14(a)(1)(i), to meet this standard the total eligible overpayments of the LEA must be at least $10,000. The Secretary believes that an LEA could repay a total eligible debt of less than $10,000, in installments if necessary, without undue financial hardship.

In addition, under proposed § 222.14(a)(1)(ii), for an LEA in a State with a maximum local real property rate (other than an LEA with boundaries that are the same as a Federal military installation), the LEA's local real property tax rate for current expenditure purposes for the preceding fiscal year would be required to be at least 90 percent of the maximum rate allowed by State law. The Secretary believes that this is a reasonable level of effort to require an LEA to make to repay its debts. For such an LEA in a State without a maximum local real property tax rate, the LEA's local real property tax rate for current expenditure purposes, for the preceding fiscal year, would be required to be at least equal to the State average local real property tax rate.

Under proposed § 222.14(b), the Secretary would use the same method to determine an LEA's tax rate for current expenditure purposes as the Secretary uses for eligibility and payments under section 8003(f) of the Act (heavily impacted LEAs).

Because an LEA's capacity to raise local revenues is determined by the level of the assessed values of its real property, as well as by the tax rate it levies, the Secretary also would consider the fiscal capacity of these LEAs under proposed § 222.14(a)(1)(iii). The Secretary would define ''fiscal capacity'' for this purpose (under proposed § 222.14(c)) to mean the equalized assessed valuation of real property per pupil (EAVPP), unless otherwise defined by State law. Under this proposed standard, the fiscal capacity of these LEAs for the preceding fiscal year would be required to be below the State average. The Secretary believes that if an LEA's fiscal capacity is greater than the State average, it would not be an undue financial burden on the LEA to increase its local revenues to repay the Impact Aid debt. The Secretary is interested in receiving comments on this fiscal capacity measure and its threshold.

Under proposed § 222.14(a)(1), an LEA with boundaries that are the same as a Federal military installation (''coterminous LEA'') would not be required to meet the local effort standards under proposed § 222.14(a)(1)(ii) and (iii). This is because most of the real property in coterminous LEAs is not subject to local real property taxes. Therefore, for these coterminous LEAs, the Secretary would consider instead their average per pupil expenditure. Under proposed § 222.14(a)(1)(iv), a coterminous LEA would qualify only if its average per pupil expenditure (PPE) for the preceding fiscal year did not exceed 125 percent of the average PPE in all LEAs in the State for that preceding fiscal year.

Finally, under proposed § 222.14(a)(2), any LEA would meet the undue financial hardship standard if the Secretary determined that neither the successor nor the predecessor LEA has the present or prospective ability to repay the eligible overpayment. The Secretary anticipates that this provision will be applicable only in extremely limited situations, such as when a debtor LEA has no present revenue and is not expected to have any future revenue.

Proposed § 222.15 describes the amount of an eligible overpayment that the Secretary forgives once an LEA has timely filed a forgiveness request and the required information and documentation. Under § 222.15(a), the Secretary would forgive an eligible overpayment in whole if the Secretary has determined that the LEA meets the undue financial hardship test under § 222.14 and the LEA's preceding year's current expenditure closing balance was five percent or less of its preceding fiscal year's total current expenditures.

The Secretary considers five percent of an LEA's total current expenditures to be a reasonable minimal amount for an LEA to carry over for a smooth transition from the end of one year to the beginning of the next. Unless an LEA has more than that amount of funds at the end of the year, the Secretary believes that it would impose an undue financial burden on the LEA to be required to repay the eligible overpayment. Therefore, for an eligible LEA with five percent or less in carryover funds at the end of the LEA's fiscal year preceding the date of the forgiveness request, the Secretary would forgive an eligible overpayment in whole.

In addition, under proposed § 222.15(a) the Secretary would forgive an eligible overpayment in whole if, in the case of an error by the Secretary, the Secretary determines that repayment by the LEA would be manifestly unjust. The Secretary anticipates that an LEA would qualify for forgiveness in whole under this special provision only on the rare occasion in which an LEA received an overpayment due to an error on the part of the Secretary that an LEA could not reasonably be expected to identify and report. For example, if the Secretary calculated a payment for an LEA using an incorrect local contribution rate, and the LEA did not know nor could it reasonably have known that the local contribution rate was too high, the resulting overpayment would be forgiven in whole by the Secretary under this standard.

Proposed § 222.15(b)(1) specifies that the Secretary will forgive an eligible overpayment in part if an LEA otherwise meets the requirements for forgiveness and the undue financial hardship test, but the LEA's preceding fiscal year's current expenditure closing balance was more than five percent of its preceding fiscal year's total current expenditures. In cases where an LEA has more than five percent carryover at the end of its preceding fiscal year, the Secretary believes that it would not be an undue financial burden for an LEA to repay all or a portion of the excess Federal funds it received. Under § 222.15(b)(2), if an LEA qualifies for forgiveness of a debt in part, the LEA would be expected to repay the amount by which its preceding fiscal year's closing balance exceeded five percent of its preceding fiscal year's total current expenditures. The Secretary would forgive the remaining amount of the LEA's eligible overpayment balance.

2. *Payments for Federal property (section 8002 of the ESEA).* In subpart B, the Secretary proposes two revisions to § 222.22, a portion of which implements the new statutory requirement that the Secretary must deduct from an LEA's section 8002 payment the amount of revenue that an LEA received during the previous fiscal year from activities conducted on eligible Federal property. The Secretary is proposing these revisions in response to public request for clarification. Paragraph (c) would be revised to clarify that the Secretary deducts these revenues from the LEA's section 8002 maximum payment amount, rather than from an LEA's section 8002 payment after any proration due to insufficient appropriations. Paragraph (d) would be revised to clarify that the Secretary does not consider Federal payments-in-lieu-of-taxes (PILOT or PILT), such as PILTs for Federal entitlement lands under Public Law 97–258 (31 U.S.C. 6901–6906), to be revenues from activities on Federal property for the purpose of this section. This is because, historically in the Impact Aid Program, Congress has not considered these types of payments as revenue resulting from activities conducted on Federal property.

In addition, a new § 222.23 would be added to subpart B to implement the new statutory method in section 8002(b)(3) of the ESEA for valuing the Federal property that is the basis for payments under section 8002 (previously section 2 of Public Law 81–874). Under section 8002(b)(3), the aggregate assessed value of eligible Federal property must be determined, by the local official responsible for assessing the value of real property in the LEA, on the basis of the current ''highest and best use'' of taxable properties ''adjacent'' to the parcel of eligible Federal property.

Proposed § 222.23(a) would require a local official first to determine a fair market value for the eligible Federal property based upon the highest and best use of the adjacent taxable parcels. The official then would be required to adjust that fair market value by any percentage, ratio, index, or other factor that the official would use, if the eligible Federal property were taxable, to determine its assessed value for the purpose of generating local real property tax revenues for current expenditures. The proposed regulation also clarifies that the official may assume that there was a transfer of ownership of the

eligible Federal property for the year for which the section 8002 assessed value is being determined.

Numerous section 8002 applicants have requested the Department to establish regulatory parameters for the ''highest and best use'' standard. In response to that request, proposed § 222.23(b) would define the terms ''adjacent'' and ''highest and best use.''

In doing so, the proposed regulation provides maximum flexibility to States and localities by basing the local official's determination of fair market value upon State or local law or guidelines if available, and by allowing consideration of the most developed and profitable use for which adjacent taxable property is physically adaptable and for which there is a need or demand for such use in the near future. The standards for ''highest and best use'' in these proposed regulations are based upon the *Uniform Appraisal Standards for Federal Land Acquisitions* (Washington, D.C.: U.S. Printing Office, 1992), which are developed by the Interagency Land Acquisition Conference and establish guidelines for Federal land acquisitions appraisals.

To address concerns articulated by applicants that this degree of flexibility could be subject to abuse by applicants, in accordance with the *Uniform Appraisal Standards* the proposed regulation also provides that a local official may not consider speculative or remote potential uses of adjacent property. In addition, if the highest and best uses of all adjacent properties are not the same, § 222.23(b) would require the local official to take into consideration the different potential uses of adjacent properties. For example, an official could not base the valuation of the entire Federal property only on the highest valued adjacent property (such as commercial property) if other adjacent properties had different potential uses (such as residential or agricultural property).

3. *Payments for children with severe disabilities (section 8003(g) of the ESEA).* A new subpart F would be added to implement the new authority in section 8003(g) of the ESEA for payments to certain LEAs for children with severe disabilities. In that subpart, proposed § 222.80 defines ''children with severe disabilities'' in a manner consistent with the definition of the term in 34 CFR § 315.4(d) of the regulations implementing the Individuals with Disabilities Education Act. Proposed § 222.81 describes the requirements that an LEA must meet to be eligible for and receive a payment under section 8003(g), including that the LEA must be eligible for a payment under section 8003(d) of the ESEA (payments for federally connected children with disabilities) for those children to be claimed as the basis for a payment under section 8003(g). Section 8003(g) specifies that eligible children must have a parent on active duty in the uniformed services with a compassionate post assignment. However, proposed § 222.81 does not include the term ''compassionate post assignment'' because no standard policy or definition regarding that term could be ascertained. Comments are invited on any measurable standard that could be used for the term.

Proposed § 222.82 explains how the Secretary would calculate the total amount of funds available for payments under section 8003(g) under the limited circumstances in which those funds are available. Proposed § 222.83 provides that the Secretary will give written notice to all potentially eligible LEAs if funds are available for payments under section 8003(g), and explains how an LEA would apply to the Secretary for those funds. Under this proposed regulation, to apply for section 8003(g) funds, an LEA would be required to submit documentation to the Secretary, within 60 days of the date of the Secretary's notice to the LEA that funds are available, detailing the total costs to the LEA of providing a free appropriate public education for the eligible children with severe disabilities.

Proposed § 222.84 establishes how the Secretary would calculate an LEA's payment under section 8003(g). Under that method, to avoid double payment for the same child, the Secretary would subtract the amount that the LEA received under section 8003(d) of the ESEA for that child. Finally, proposed § 222.85 clarifies that an LEA must use the funds it receives under section 8003(g) for the reimbursement of total costs, reported in its section 8003(g) application, of providing an educational program outside the schools of the LEA for the federally connected children with severe disabilities claimed under section 8003(g).

4. *Withholding and related procedures for Indian policies and procedures (sections 8004(d)(2) and 8004(e) (8)–(9) of the ESEA).* Proposed §§ 222.114–222.122 would be added to subpart G to implement the Secretary's expanded enforcement authority for Indian policies and procedures in sections 8004(d)(2) and 8004(e) (8)–(9) of the ESEA. Section 8004(a) of the ESEA, like the previous Impact Aid law, requires LEAs to establish certain Indian policies and procedures (IPPs), including policies and procedures to ensure that children residing on Indian lands participate in programs and activities on an equal basis with all other children, and that parents of the children residing on Indian lands and Indian tribes have an opportunity to present their views on those programs and activities.

Section 8004(d)(2) has expanded the Secretary's previous authority to enforce the implementation of IPPs. Under section 8004(d)(2), the Secretary may now take any appropriate action to enforce the IPP requirements, including withholding section 8003 funds from the LEA, after affording an opportunity for interested parties to present their views. In addition, section 8004(e)(8) has expanded the Secretary's previous withholding authority by requiring the Secretary to withhold an LEA's entire section 8003 payment, rather than only the portion of that payment that represents an increase due to a federally connected child's residence on Indian lands.

Because most IPP issues are resolved through technical assistance provided by the Impact Aid Program, the Secretary does not believe that it will be necessary to exercise this withholding authority in most cases. However, the Secretary's intent in publishing these regulations is to adopt clear and fair withholding procedures for LEAs and Indian tribes in the event of a withholding action. Comments and suggestions are invited on whether these proposed regulations are clear and whether they could be simplified.

To implement these expanded enforcement provisions, the Secretary proposes to revise § 222.95(g) of the current regulations, and to add new §§ 222.114–222.122. Section 222.95(g) currently requires an LEA that amends its IPPs following its annual review of those policies and procedures to send a copy of the amended IPPs to the Impact Aid Program Director for approval and to the affected tribe or tribes. That section would be revised to establish a definite time limit within which the LEA must send a copy of the amended IPPs to the Director and affected tribe or tribes, which would be within 30 days of the LEA's amendment.

New §§ 222.114–222.122 would describe withholding procedures implementing sections 8004(d)(2) and 8004(e)(8) of the ESEA. Proposed § 222.114 provides that the Assistant Secretary uses any appropriate actions to enforce IPP statutory and regulatory requirements, including the withholding of funds in accordance with §§ 222.115–222.122, after affording an opportunity to the affected LEA, parents, and Indian tribe or tribes to present their views.

Proposed § 222.115 describes the circumstances under which the Assistant Secretary will withhold payments that an LEA otherwise is eligible to receive under section 8003 of the Act. As described in proposed § 222.115(a), payments are withheld if the Assistant Secretary determines it is necessary to enforce IPP statutory or regulatory requirements. In addition, where a tribal complaint has resulted in an IPP hearing, proposed § 222.115(b) explains that the Assistant Secretary withholds payments if an LEA rejects the final determination of the Assistant Secretary, or refuses to implement the required remedy within the time established and the Assistant Secretary determines that the LEA would not otherwise undertake the required remedy within a reasonable time.

Proposed § 222.115 also clarifies that, with either type of a withholding action (that is, with or without a previous IPP hearing), the Assistant Secretary would not withhold payments under the specific circumstances described in proposed § 222.120. Those circumstances would include: (1) where the LEA has received a waiver from compliance with the IPP requirements from the affected tribe or tribes because of satisfaction with the LEA's provision of educational services to its federally connected children (§ 222.120(a)); where the tribe submits to the Assistant Secretary a written request not to withhold the LEA's section 8003 payments (§ 222.120(b)); where the Assistant Secretary determines that withholding section 8003 payments during the course of the school year would substantially disrupt the educational programs of the LEA (§ 222.120(c)); or where the LEA rejects the final determination of the Assistant Secretary and the tribe elects to have educational services provided by a Bureau of Indian Affairs School but some Indian students remain at the LEA (§ 222.120(d)).

Proposed § 222.116 describes how the Assistant Secretary initiates an IPP withholding proceeding. Under the proposed process, the Assistant Secretary would send a written notice of intent to withhold payments to the LEA and the affected Indian tribe or tribes, describing how the LEA has failed to comply with the applicable IPP requirements and advising the LEA of its rights under the withholding procedures.

Proposed § 222.117 describes the procedures the Assistant Secretary follows after issuing a notice of intent to withhold payments to an LEA. Proposed § 222.117(b) clarifies that an LEA that receives a notice of intent to withhold payments from the Assistant Secretary is not entitled to an administrative hearing under section 8011 of the ESEA and subpart J of the regulations.

Proposed § 222.117(c) provides that an LEA that already has participated in an IPP hearing, but rejects or refuses to implement the Assistant Secretary's final determination, would have the opportunity to justify by a timely filed written explanation with the Assistant Secretary why that withholding should not occur. The written explanation and any supporting documentation would be required to be filed within 10 days from the date of the LEA's receipt of the Assistant Secretary's written notice of intent to withhold funds.

On the other hand, if an LEA has not yet participated in a hearing concerning its compliance with IPP requirements, § 222.117(d) would permit the LEA an opportunity for a withholding hearing. An LEA would be required to file a written hearing request within 30 days from the date of its receipt of the Assistant Secretary's notice of intent to withhold funds.

Proposed § 222.118 describes how IPP withholding hearings will be conducted, which will be by a hearing examiner, with the opportunity for the parties to present their views in writing or orally. Under these procedures, the hearing examiner would make an initial withholding decision based upon written findings, which would be sent to both parties and to the affected tribe or tribes (§ 222.118(f)). That initial withholding determination would constitute the Secretary's final withholding decision without any further proceedings, unless one of the parties to the withholding hearing requests the Secretary's review of the hearing examiner's initial decision or the Secretary otherwise determines to review the decision.

Proposed § 222.119 describes which payments are subject to being withheld due to noncompliance with IPP requirements. Once a final withholding decision has been issued, all of an LEA—s section 8003 payments would be withheld under this provision, regardless of fiscal year, until the LEA either documents compliance, or exemption from compliance under proposed § 222.120.

As discussed previously, proposed § 222.120 clarifies the circumstances that exempt an LEA from a withholding action. One of those circumstances arises if the affected tribe or tribes files a written request that an LEA's section 8003 payments not be withheld. The Secretary encourages Indian tribes to make any such request as promptly as possible after receiving a notice of intent of withholding, to avoid any unnecessary administrative withholding proceedings and possible disruption to the LEA—s payments. If an Indian tribe wishes to make such a request, proposed § 222.121 explains the requirements that apply.

Finally, proposed § 222.122 clarifies the procedures that are followed if the Assistant Secretary determines not to withhold an LEA—s funds. The Assistant Secretary would notify the LEA and the affected Indian tribe or tribes in writing that the payments will be not be withheld, with an explanation of the reasons for that decision.

5. *Determinations under section 8009 of the ESEA.* Section 222.161 of subpart K would be revised to implement new terms used in section 8009 of the ESEA by adding definitions of the following three terms: local tax revenues, local tax revenues covered under a State equalization program, and total local tax revenues. Under section 8009, a State may take into consideration certain Impact Aid payments in allocating State aid if the Secretary determines that the State has a State aid program that is designed to equalize expenditures among the LEAs in the State.

The term ''local tax revenues'' would be defined to mean compulsory charges levied by an LEA, intermediate school district or other local governmental entity on behalf of an LEA for current expenditures for educational services. The term would be defined to include the proceeds of ad valorem taxes, sales and use taxes, income taxes and other taxes and, where a State funding formula requires a local contribution equivalent to a specified mill tax levy on taxable real or personal property, any revenues recognized by the State as satisfying that local contribution requirement.

In addition, the term ''local tax revenues covered under a State equalization program'' would be defined as local tax revenues contributed to or taken into consideration in a State aid program, but excluding all revenues from State and Federal sources. Finally, a definition would be added of the term ''total local tax revenues'' to mean all local tax revenues including revenues for education programs for children needing special services, vocational education, transportation, and the like but excluding all revenues from State and Federal sources.

Administrative Procedures

1. *Administrative hearings and judicial review (section 8011 of the ESEA).* Several changes would be made in subpart J to improve or clarify the administration of Impact Aid

administrative hearings. Section 222.151 would be revised to require an applicant's written request for an administrative hearing following an adverse action to be filed within 30 days of notice of that action, rather than within 60 days as is currently allowed. This change is proposed to expedite the Department's debt collection process so that the recovered funds can be redistributed more quickly to all eligible Impact Aid applicants. Because this provision would limit the current time period in which applicants adversely affected by Departmental action must file a hearing request, but could provide an overall benefit to all eligible Impact Aid applicants, the Secretary is particularly interested in receiving comments on this proposed provision.

Section 222.152, concerning requested reconsiderations, would be revised to clarify that either the Secretary, or the Secretary's delegate (such as the Assistant Secretary for Elementary and Secondary Education or the Director of the Impact Aid Program), could make reconsideration determinations. In addition, § 222.154 would be revised to require any party filing a written submission by facsimile transmission (FAX) in the course of an Impact Aid administrative hearing proceeding to file a follow-up hard copy within a reasonable period of time. This is a change from the current regulations, which permit the Secretary or an administrative law judge (ALJ) to request such a copy, but do not require a hard copy in all instances. The change is proposed to facilitate the operation of Impact Aid administrative hearing procedures and ensure that original signed documents are consistently in the hearing record.

Section 222.157 would be revised in paragraph (a) to require an ALJ to issue an initial, rather than a recommended, decision. This is a change from the current regulations, which allow an ALJ to issue either an initial decision that becomes final without further Secretarial review (in the absence of an appeal or independent Secretarial review), or a recommended decision requiring Secretarial review. This change would expedite the administrative hearing process for applicants and provide more consistency to the administrative hearing procedures, while still preserving the parties' appeal rights. Section 222.157(a) also would clarify that when an initial decision becomes final without Secretarial review, the Department's Office of Hearings and Appeals will notify the parties of the finality of that decision. In addition, in accordance with the Department's longstanding policy, § 222.157(b) would be revised to clarify that any party (not just the applicant) may request Secretarial review of an initial decision.

Finally, § 222.158 would be revised correspondingly to reflect that the Secretary's review would be of an ALJ's initial decision, and to clarify that the Secretary mails to each party written notice of the final decision.

2. *Determinations under section 8009 of the ESEA.* Subpart K of the regulations (Determinations under Section 8009 of the Act) would be revised to clarify the specific procedures to be followed when a proceeding is initiated under section 8009 of the ESEA. Section 222.164 would be amended in paragraph (a)(2) to provide that whenever a proceeding is initiated under section 8009 of the ESEA, the initiating party would be required to give adequate notice to the State and all LEAs in the State and provide them with a complete copy of the submission initiating the proceeding. In addition, the party initiating the proceeding would be required to notify the State and all LEAs in the State of their right to request from the Secretary, within 30 days of the initiation of a proceeding, the opportunity to present their views before the Secretary makes a determination.

These steps would enable the Department to make more timely certification determinations. Section 8009(b)(1) of the ESEA is changed from the previous Impact Aid law (section 5(d)(2) of Pub. L. 81–874), in that section 8009(b)(1) prohibits a State from reducing its State aid payments due to Impact Aid before certification by the Secretary. Therefore, to enable States to make timely State aid payments to LEAs without unnecessary adjustments, it is essential that the Department make certification determinations as rapidly as possible once a proceeding is initiated.

Section 222.164(b)(5) would be revised to clarify the predetermination procedures that the Secretary follows when a party requests the opportunity to present views before the Secretary makes a determination. Specifically, upon receipt of a timely request for a predetermination hearing, the Secretary would notify all LEAs and the State of the time and place of the predetermination hearing. The proposed regulation clarifies that predetermination hearings are informal and any LEA and the State are free to participate whether or not they requested the predetermination hearing. Under this proposed regulation, at the conclusion of the predetermination hearing, the Secretary would hold the record open for 15 days for the submission of post-hearing comments. The Secretary could extend the period for post-hearing comments for good cause for up to an additional 15 days.

In addition, the proposed revisions to § 222.164(b)(5) would clarify the Secretary's flexible approach to predetermination hearings for States and local school districts, under which an alternative to a predetermination hearing is allowed for the presentation of views, under certain circumstances, before the Secretary makes a determination. Under this alternative procedure, if the party or parties requesting the predetermination hearing agree, they may present their views to the Secretary exclusively in writing. This procedure saves the State and LEAs both time and cost, and reflects the current practice of the Secretary. Under this proposed regulation, the Secretary would notify all LEAs and the State that this alternative procedure is being followed. The proposed regulation would give those LEAs and the State up to 30 days from the date of the notice in which to submit their views in writing. Any LEA or the State would be permitted to submit its views in writing within the specified time, regardless of whether it requested the opportunity to present its views.

Finally, proposed § 222.165, concerning administrative appeals of section 8009 determinations, would be revised. Section 222.165(e) would be revised in accordance with applicable legal principles to specify that the ALJ conducting the appeal is bound by all applicable statutes and regulations and may neither waive them nor rule them invalid.

Section 222.165(f) would be revised to clarify that a follow-up hard copy of a facsimile transmission must be filed within a reasonable period of time following that transmission. Currently there is no time requirement for the filing of a follow-up hard copy. This change is proposed to be consistent with other Impact Aid facsimile transmission filing requirements.

In addition, § 222.165(h) would be revised generally to provide a more expedited hearing process for States and LEAs, and at the same time preserve their appeal rights. That provision would specify that appeals to the Secretary of initial decisions and the finality of initial decisions under section 8009 of the ESEA would be governed by §§ 222.157(b), 222.158 and 222.159 of the general Impact Aid administrative hearing procedures in subpart J. Under those procedures, an ALJ's initial decision automatically constitutes the Secretary's final decision

without any further proceedings unless the decision is appealed by a party or the Secretary decides to review the initial decision. This would be a change from current hearing practice under section 5(d)(2) of Pub. L. 81–874 and section 8009 of the ESEA, under which an ALJ's decision must be certified to the Secretary before it becomes final.

Executive Order 12866

1. Assessment of Costs and Benefits

These proposed regulations have been reviewed in accordance with Executive Order 12866. Under the terms of the order, the Secretary has assessed the potential costs and benefits of this regulatory action.

The potential costs and benefits associated with the proposed regulations are minimal and to the extent there are costs, the costs result from the statutory requirements and regulations determined by the Secretary to be necessary for administering these programs effectively and efficiently.

In assessing the potential costs and benefits—both quantitative and qualitative—of these proposed regulations, the Secretary has determined that the benefits of the proposed regulations justify the costs. A further discussion of the potential costs and benefits of these proposed regulations is contained in the summary below.

The Secretary also has determined that this regulatory action does not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

To assist the Department in complying with the specific requirements of Executive Order 12866, the Secretary invites comments on whether there may be further opportunities to reduce any potential costs or increase potential benefits resulting from these proposed regulations without impeding the effective and efficient administration of the program.

Summary of Potential Costs and Benefits of Regulatory Provisions Discussed Above

The following is a summary of the potential costs and benefits of these proposed regulations:

Overpayment Forgiveness Requests (§ 222.13(c))

This proposed provision would require an LEA seeking forgiveness of an overpayment to provide certain financial and real property taxation information in support of its request. The statutory authority to forgive Impact Aid overpayments applies only in exceptional circumstances—error of the Secretary, or error of an LEA where repayment would result in undue financial hardship and seriously harm the LEA's educational program. In exercising this permissive authority, it is important for all applicants that the Secretary establish a reasonable test to measure undue hardship and financial harm that may be objectively and uniformly applied.

Many alternative and complex standards could be proposed. However, because most LEAs derive revenue from real property taxes, the proposed test (where possible) focuses simply on an LEA's ability to raise to revenues from real property taxation to repay the debt, and requests the minimum data necessary for the Secretary to make a decision on that basis. The potential benefit to an LEA of this provision, which is the partial or total forgiveness of a debt owed to the Department, far outweighs the minimal burden of providing this information.

Valuation of Federal Property for Section 8002 Purposes (§ 222.23)

This proposed regulation standardizes the method local officials to use in valuing Federal property for the purposes of an LEA's section 8002 application. The statute requires that the aggregate assessed value of the Federal property be determined by a local official on the basis of the current highest and best of the adjacent property and provided to the Secretary.

Section 8002 applicants have expressed significant concern to the Department that there is no consistent method for local officials to follow in valuing the Federal property in their various jurisdictions, and that the limited section 8002 funds therefore will be inequitably distributed. This regulation addresses the concerns of those LEAs by providing a standard method for local officials to follow in determining the aggregate assessed value of the Federal property, and standard definitions for two critical terms, ''adjacent'' and ''highest and best use.'' In defining the latter term, the proposed regulation provides maximum flexibility to States and localities by basing the local official's determination of fair market value upon State or local guidelines if available.

Although there may some increased burden on local officials if they are not currently using any particular method to arrive at a valuation of the Federal property, the benefit to all section 8002 applicants in having a minimally uniform standard that allows for local differences and will result in a fair distribution of funds far outweighs any potential burden on those local officials.

Withholding and Related Procedures for Indian Policies and Procedures (§§ 222.114–222.122)

These proposed regulations implement the Secretary's expanded enforcement authority for Indian policies and procedures in sections 8004(a)(2) and 8004(e)(8)–(9) of the ESEA, which includes the authority to withhold section 8003 payments from LEAs under certain circumstances. On September 29, 1995, the Secretary published final technical rules in the Federal Register (60 FR 50774–50800), which contained detailed rules governing IPPs. Those rules included complaint and hearing procedures (§§ 222.102–222.113) that are available to Indian tribes if an LEA has not complied with IPP requirements. They did not provide specific procedures for the Secretary to follow, however, if it became necessary to withhold section 8003 payments from an LEA to obtain that compliance.

Because the Impact Aid Program provides technical assistance to LEAs, parents, and Indian tribes to assure compliance with IPP requirements, the Secretary does not anticipate that it will be necessary to use these proposed withholding procedures in most cases. In the past, few complaints have been filed and all have been resolved without the necessity for reaching a withholding determination.

In the unlikely event that it becomes necessary for the Secretary to issue a withholding determination, however, these procedures would be necessary so that the affected LEA and Indian tribe or tribes clearly know what procedures to follow. Any burden caused by these procedures is outweighed by the benefit to both LEAs and Indian tribes of having these procedures in place.

Requests for an Administrative Hearing Following an Adverse Action (§ 222.151)

This provision would change the time within which an LEA may file a request for an administrative hearing following an adverse action from 60 days to 30 days. This change is being proposed to expedite the Department's debt collection process so that funds recovered from Impact Aid overpayments may be redistributed more rapidly to all eligible Impact Aid applicants. Thirty days is a reasonable time period for LEAs to preserve their appeal rights, and any burden caused by this shorter period is outweighed by the benefit to all applicants of receiving a more rapid redistribution of funds.

Notification of Initiation of Section 8009 Proceeding (§ 222.164(a)(2))

This proposed regulation would require any party initiating a certification determination under section 8009 of the ESEA to give notice of the initiation of that proceeding to the State and LEAs in the State, and to provide those entities with a complete copy of the submission initiating the proceeding. Currently, when a proceeding is initiated, the Impact Aid Program provides notice of the initiation, and any interested LEA (or State) must contact the initiating party independently to obtain a copy of the initiating submission (including the equalization data). This process can be cumbersome and time-consuming.

The statute now has been amended to prohibit a State from reducing its State aid payments due to Impact Aid before certification by the Secretary. Therefore, to enable States to make timely State aid payments to LEAs without unnecessary adjustments, it is essential that the Department make certification determinations as rapidly as possible once a proceeding is initiated. Although requiring the initiating party to provide notice of that initiation and a copy of its submission to the State and all LEAs will cause some burden, that burden is outweighed by more rapid certification determinations and the consequent ability of the State to make State aid payments on a more timely basis.

2. Clarity of the Regulations

Executive Order 12866 requires each Federal agency to write regulations that are easy to understand.

The Secretary invites comment on how to make these regulations easier to understand, including answers to questions such as the following: (1) Are the requirements in the regulations clearly stated? (2) Do the regulations contain technical terms or other wording that interferes with the clarity? (3) Does the format of the regulations (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce their clarity? Would the regulations be easier to understand if they were divided into more (but shorter) sections? (A ''section'' is preceded by the symbol ''§ '' and a numbered heading; for example ''§ 222.1 *What is the scope of this part?*'') (4) Is the description of the proposed regulations in the ''Supplementary Information'' section of this preamble helpful in understanding the proposed regulations? How could this description be more helpful in making the proposed regulations easier to understand? (5) What else could the Department do to make the regulations easier to understand?

A copy of any comments that concern whether these proposed regulations are easy to understand should also be sent to Stanley M. Cohen, Regulations Quality Officer, U.S. Department of Education, 600 Independence Avenue, S.W. (Room 5121, FOB–10), Washington, DC, 20202–2241.

Regulatory Flexibility Act Certification

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

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

Paperwork Reduction Act of 1995

As described below, proposed §§ 222.83(b) and (c), 222.95(g), and 222.164(a)(2) and (b), contain information collection requirements. As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the Department of Education has submitted a copy of these sections to the Office of Management and Budget (OMB) for its review under that Act.

Collection of Information: Impact Aid: Payments to Local Educational Agencies for Children with Severe Disabilities under Section 8003(g) of the Act (Part 222, Subpart F): Under proposed § 222.83(b) and (c) (How does an eligible LEA apply for a payment under section 8003(g)?), an LEA that wishes to apply under section 8003(g) of the ESEA for special funds that may be available for certain federally connected children with severe disabilities is required to submit to the Secretary information detailing the total costs to the LEA of providing a free appropriate public education for those children. That information may include: (1) for the costs of the outside entity providing the educational program for those children, copies of invoices, vouchers, tuition contracts, and other similar documents showing the signature of an official or authorized employee of the outside entity; and (2) for the additional costs, if any, of the LEA related to that educational program, copies of invoices, check receipts, contracts, and other similar documents showing the signature of an official or authorized employee of the LEA.

The likely respondents to this collection of information are LEAs that have federally connected children with severe disabilities whose parents are on active duty in the uniformed services and the outside entity or institution providing the educational program for those children. The information submitted is used to calculate the amount of the LEA's payment under section 8003(g) of the Act.

We estimate that approximately 24 LEAs may apply for funds under section 8003(g), and each application will take an average of 2 hours to prepare. Therefore, the total annual reporting and recordkeeping burden that will result from the collection of this information is 48 burden hours (24 LEAs, multiplied by 1 application, multiplied by 2 burden hours for preparing each application).

Collection of Information: Impact Aid: Special Provisions for Local Educational Agencies that Claim Children Residing on Indian Lands (Part 222, Subpart G): An LEA is required, as a part of its application for funds under section 8003 of the ESEA, to submit certain policies and procedures in accordance with section 8004 of the ESEA to ensure equal participation of Indian children and consultation with and involvement of their parents and Indian tribes (IPPs). Under proposed § 222.95(g) (How are Indian policies and procedures reviewed to ensure compliance with the requirements in section 8004(a) of the Act?), an LEA would have 30 days to send a copy of any amendment to its IPPs to the Director of the Impact Aid Program and the affected Indian tribe or tribes. This provision would not change the paperwork burden for IPPs, which was approved previously as a part of the section 8003 application under OMB #1810–0036 (942,915 total annual hours for all applicants, as revised downward due to changes in the Impact Aid law (based upon an average of .109 annual hours per parent response per child, and an average of 303 annual hours per LEA annual response per application)).

Collection of Information: Impact Aid: Determinations under Section 8009 of the Act (Part 222, Subpart K): Under proposed § 222.164(a)(2) (What procedures does the Secretary follow in making a determination under section 8009?), the party initiating an equalization proceeding under section 8009 of the ESEA must provide the State and all LEAs in the State with a complete copy of the submission initiating the proceeding. In addition, the party initiating the proceeding must notify the State and all LEAs in the State

of their right to request from the Secretary the opportunity to present their views to the Secretary before the Secretary makes a determination.

The likely respondents to these third-party disclosure requirements are States and LEAs that may initiate equalization proceedings. The information that they are required to disclose is used by interested parties to determine whether to request the opportunity to present their views as to whether the State meets the statutory equalization criteria. If a State meets that criteria, it may reduce State aid payments to LEAs that receive Impact Aid funds.

We estimate that equalization proceedings will be initiated in an average of four States per year, which have an average of 125 LEAs to which the required information must be disclosed, and that the disclosure will require an average of .02 hour per disclosure to prepare and mail. Therefore, the total annual reporting and recordkeeping burden that will result from this disclosure requirement is 10.0 burden hours (4 States, multiplied by 125 LEAs, multiplied by .02 hour for preparing and mailing each notice).

In addition, when an equalization proceeding is initiated, certain information must be submitted to the Secretary under proposed § 222.164(b) to enable the Secretary to determine whether the State meets the statutory standard for certification. The likely respondents to this collection requirement are States seeking certification of their equalization plans. The information that they are required to submit is used by the Secretary to determine whether the State's equalization plan meets the statutory requirements for certification so that the State may take Impact Aid payments into account in distributing State aid.

We estimate that equalization proceedings will be initiated in an average of 4 States per year, and that the data submission to the Secretary will require an average of 45.25 hours per collection. Therefore, the total annual reporting and recordkeeping burden that will result from this collection requirement is 181.0 burden hours (4 States, multiplied by 1 annual submission, multiplied by 45.25 hours for preparation and mailing of each submission).

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, OMB, Room 10235, New Executive Office Building, Washington, DC 20503; Attention: Desk Officer for U.S. Department of Education.

The Department considers comments by the public on these proposed collections of information in:

- Evaluating whether the proposed collections of information are necessary for the proper performance of the functions of the Department, including whether the information will have practical utility;
- Evaluating the accuracy of the Department's estimate of the burden of the proposed collections of information, including the validity of the methodology and assumptions used;
- Enhancing the quality, usefulness, and clarity of the information to be collected; and
- Minimizing 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 form of information technology; e.g., permitting electronic submission of responses.

OMB is required to make a decision concerning the collection of information contained in these proposed regulations between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment to the Department on the proposed regulations.

Invitation to Comment: Interested persons are invited to submit comments and recommendations regarding these proposed regulations. The Secretary is particularly interested in comments on proposed §§ 222.12–222.15 (implementing the overpayment forgiveness provision), § 222.81 (describing eligibility standards for payments for children with severe disabilities); §§ 222.114–222.122 (implementing Indian policy and procedures withholding proceedings), and § 222.151(b)(1) (changing the time within which an administrative hearing request must be filed from 60 to 30 days following an adverse action).

All comments submitted in response to these proposed regulations will be available for public inspection during and after the comment period, in Room 4200, Portals Building, 1250 Maryland Avenue, S.W., Washington, DC., between the hours of 8:30 a.m. and 4 p.m., Monday through Friday of each week except Federal holidays.

List of Subjects in 34 CFR Part 222

Education, Education of children with disabilities, Elementary and secondary education, Federally affected areas, Grant programs—education, Indians—education, Public housing, Reports and recordkeeping requirements, School construction.

Dated: October 1, 1996.

(Catalog of Federal Domestic Assistance Number 84.041, Impact Aid)

Richard W. Riley,

Secretary of Education.

The Secretary proposes to amend Part 222 of Title 34 of the Code of Federal Regulations as follows:

PART 222—IMPACT AID PROGRAMS

1.–2. The authority citation for Part 222 continues to read as follows:

Authority: 20 U.S.C. 7701–7714, unless otherwise noted.

3. Section 222.4 is revised to read as follows:

§ 222.4 How does the Secretary determine when an application is timely filed?

(a) To be timely filed under § 222.3, an application must be received by the Secretary, or mailed, on or before the applicable filing date.

(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.

(Authority: 20 U.S.C. 7705)

Note to Paragraph (b)(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.

§ 222.11 [Amended]

4. In § 222.11, the introductory language is amended by removing ''Except as otherwise provided in section 8012'', and by adding in its place ''Except as otherwise provided in § 222.12,''.

5. Section 222.13 is redesignated as § 222.16, and new §§ 222.12–222.15 are added to read as follows:

§ 222.12 What overpayments are eligible for forgiveness under section 8012 of the Act?

(a)(1) Except as provided in paragraph (a)(2) of this section, the Secretary considers the following overpayments as eligible for forgiveness under section 8012 of the Act (''eligible overpayment''):

(i) An overpayment balance that remains owing on or after [insert the 30th day from the date of publication of the final regulations in the Federal Register], and that is more than a local educational agency (LEA) was eligible to receive for a particular fiscal year under Public Law 81–874, Public Law 81–815, or the Act.

(ii) An overpayment amount that is more than an LEA was eligible to receive for a particular fiscal year under Public Law 81–874, Public Law 81–815, or the Act, and that—

(A) Is the subject of a written request for forgiveness filed by the LEA before [insert the 30th day from the date of publication of the final regulations in the Federal Register]; or

(B) Is the subject of a timely written request for an administrative hearing or reconsideration, and has not previously been reviewed under §§ 222.12–222.15.

(2) The Secretary does not consider the following overpayments to be eligible for forgiveness under section 8012 of the Act:

(i) Any overpayment under section 7 of Public Law 81–874 or section 16 of Public Law 81–815.

(ii) An amount received by an LEA, as determined under section 8003(g) of the Act, which authorizes payments to LEAs for certain federally connected children with severe disabilities (implemented in subpart F of these regulations), that exceeds the LEA's maximum basic support payment under section 8003(b) of the Act.

(iii) Any overpayment received under the following provisions that was caused by an LEA's failure to expend or account for funds properly in accordance with the applicable law and regulations:

(A) Section 8003(d) of the Act (implemented in subpart D of these regulations) or section 3(d)(2)(C) of Public Law 81–874 for certain federally connected children with disabilities.

(B) Section 8003(g) of the Act.

(b) The Secretary applies §§ 222.13–222.15 in forgiving, in whole or part, an LEA's obligation to repay an eligible overpayment that resulted from error either by the LEA or the Secretary.

(Authority: 20 U.S.C. 7712)

§ 222.13 What requirements must a local educational agency meet for an eligible overpayment to be forgiven in whole or part?

(a) The Secretary forgives an eligible overpayment, in whole or part as described in § 222.15, if—

(1) The LEA files, in accordance with paragraph (b) of this section—

(i) A request for forgiveness; and

(ii) The information and documentation described in paragraph (c) of this section; and

(2)(i) The Secretary determines under § 222.14, in the case either of an LEA's or the Department's error, that repayment of the LEA's total eligible overpayments will result in an undue financial hardship on the LEA and seriously harm the LEA's educational program; or

(ii) In the case of the Department's error, the Secretary determines on a case-by-case basis that repayment would be manifestly unjust (''manifestly unjust repayment exception'').

(b)(1) Except for an overpayment described in paragraph (2) of this section, an LEA must submit to the Impact Aid Program a written request for forgiveness no later than 30 days from the LEA's initial receipt of a written notice of the overpayment.

(2) For an overpayment for which an LEA has submitted a written request for forgiveness before [insert the 30th day from the date of publication of the final regulations in the Federal Register], the information and documentation described in paragraph (c) of this section must be submitted no later than [insert the 60th day from the date of publication of the final regulations in the Federal Register].

(3) An LEA must submit the information and documentation described in paragraph (c) of this section no later than the applicable time limits described in paragraph (b)(1) or (2) of this section, or other time limit established in writing by the Secretary due to lack of availability of the information and documentation.

(c)(1) Every LEA requesting forgiveness must submit the following information and documentation (as applicable) for the fiscal year immediately preceding the date of the request for forgiveness (''preceding fiscal year''):

(i) A copy of the LEA's annual financial report to the State.

(ii) The LEA's local real property tax rate for current expenditure purposes, as described in § 222.14(b).

(iii) The maximum local real property tax rate for current expenditure purposes allowed by State law, or if there is no State maximum, the average local real property tax rate of all LEAs in the State.

(iv) For an LEA whose boundaries are the same as a Federal military installation—

(A) The average per pupil expenditure (PPE) of the LEA; and

(B) The average PPE in all LEAs in the State.

(v) The equalized assessed valuation of real property per pupil (EAVPP) (or other measure of fiscal capacity as defined by the State) for the LEA, and the average of that measure for all LEAs in the State.

(2) An LEA requesting forgiveness under § 222.13(a)(2)(ii) (manifestly unjust repayment exception), or § 222.14(a)(2) (no present or prospective ability to repay), must submit written information and documentation (in addition to that described in paragraph (c)(1) of this section) in support of its request for forgiveness under those provisions.

(d)(1) A request for forgiveness of an overpayment under this section does not extend the time within which an applicant must file a request for an administrative hearing under § 222.151, unless the Secretary (or the Secretary's delegatee) extends that time limit in writing.

(2) A request for an administrative hearing under § 222.151, or for reconsideration under § 222.152, does not extend the time within which an applicant must file a request for forgiveness under this section, unless the Secretary (or the Secretary's delegatee) extends that time limit in writing.

(Authority: 20 U.S.C. 7712)

§ 222.14 How does the Secretary determine undue financial hardship and serious harm to a local educational agency's educational program?

(a) The Secretary determines that repayment of an eligible overpayment will result in undue financial hardship on the LEA and seriously harm its educational program if the LEA meets the requirements in paragraph (a)(1) or (2) of this section:

(1) An LEA qualifies under paragraph (a) of this section if—

(i) The sum of the LEA's eligible overpayments on the date of its request is at least $10,000;

(ii)(A) For an LEA in a State with a maximum local real property tax rate (except for an LEA described in paragraph (a)(1)(iv) of this section), the LEA's local real property tax rate for current expenditure purposes, for the preceding fiscal year, is at least 90% of the maximum rate allowed by State law; or

(B) For an LEA in a State without a maximum local real property tax rate (except for an LEA described in paragraph (a)(1)(iv) of this section), the LEA's local real property tax rate for current expenditure purposes, for the preceding fiscal year, is at least equal to the State average local real property tax rate;

(iii) For an LEA described in paragraph (a)(1)(ii) of this section, the LEA's fiscal capacity, for the preceding fiscal year, is below the State average; and

(iv) For an LEA with boundaries that are the same as a Federal military installation, the average per pupil expenditure (PPE) of the LEA for the preceding fiscal year does not exceed 125% of the average PPE in all LEAs in the State for that preceding fiscal year.

(2) In the alternative, an LEA qualifies under paragraph (a) of this section if neither the successor nor the predecessor LEA has the present or prospective ability to repay the eligible overpayment.

(b) The Secretary uses the following methods to determine a tax rate for the purposes of paragraph (a)(1) (ii) and (iii) of this section:

(1) If an LEA is fiscally independent, the Secretary uses actual tax rates if all the real property in the taxing jurisdiction of the LEA is assessed at the same percentage of true value. In the alternative, the Secretary may compute a tax rate for fiscally independent LEAs by using the methods described in §§ 222.67–222.69.

(2) If an LEA is fiscally dependent, the Secretary imputes a tax rate using the method described in § 222.70(b).

(c) ''Fiscal capacity'' for the purpose of paragraph (a)(1)(v) of this section means the equalized assessed valuation of real property per pupil (EAVPP), unless otherwise defined by the State.

(Authority: 20 U.S.C. 7712)

§ 222.15 What amount does the Secretary forgive?

For an LEA that meets the requirements of § 222.13(b) (timely filed forgiveness request and information and documentation), the Secretary forgives an eligible overpayment as follows:

(a) *Forgiveness in whole.* The Secretary forgives the eligible overpayment in whole if the Secretary determines that the LEA meets—

(1) The requirements of § 222.14 (undue financial hardship), and the LEA's current expenditure closing balance for the LEA's fiscal year immediately preceding the date of its request for forgiveness (''preceding fiscal year'') is five percent or less of its total current expenditures (TCE) for that year; or

(2) The manifestly unjust repayment exception in § 222.13(a)(2)(ii).

(b) *Forgiveness in part.* (1) The Secretary forgives the eligible overpayment in part if the Secretary determines that the LEA meets the requirements of § 222.14 (undue financial hardship), but the LEA's preceding fiscal year's current expenditure closing balance is more than five percent of its total current expenditures (TCE) for that year.

(2) For an eligible overpayment that is forgiven in part, the Secretary—

(i) Requires the LEA to repay the amount by which the LEA's preceding fiscal year's current expenditure closing balance exceeded five percent of its preceding fiscal year's total current expenditures (''calculated repayment amount''); and

(ii) Forgives the difference between the calculated repayment amount and the LEA's total overpayments.

(3) For the purposes of this section, ''current expenditure closing balance'' means an LEA's closing balance before any revocable transfers to non-current expenditure accounts, such as capital outlay or debt service accounts.

Example: An LEA that timely requests forgiveness has two overpayments of which portions remain owing on the date of its request—one of $200,000 and one of $300,000. Its preceding fiscal year's closing balance is $250,000 (before a revocable transfer to a capital outlay or debt service account); and 5 percent of its TCE for the preceding fiscal year is $150,000.

The Secretary calculates the amount that the LEA must repay by determining the amount by which the preceding fiscal year's closing balance exceeds 5 percent of the preceding year's TCE. This calculation is made by subtracting 5 percent of the LEA's TCE ($150,000) from the closing balance ($250,000), resulting in a difference of $100,000 that the LEA must repay. The Secretary then totals the eligible overpayment amounts ($200,000 + $300,000), resulting in a total amount of $500,000. The Secretary subtracts the calculated repayment amount ($100,000) from the total of the two overpayment balances ($500,000), resulting in $400,000 that the Secretary forgives.

(Authority: 20 U.S.C. 7712)

6. Section 222.22 is amended by revising paragraphs (c) and (d) to read as follows:

§ 222.22 How does the Secretary treat compensation from Federal activities for purposes of determining eligibility and payments?

* * * * *

(c) If an LEA described in paragraph (a) of this section received revenue described in paragraph (b)(1) of this section during the preceding fiscal year that is less than the maximum payment amount under section 8002(b) for the fiscal year for which the LEA seeks assistance, the Secretary reduces that maximum payment amount by the amount of that revenue received by the LEA.

(d) For purposes of this section, the amount of revenue that an LEA receives during the previous fiscal year from activities conducted on Federal property does not include the following:

(1) Payments received by the agency from the Secretary of Defense to support—

(i) The operation of a domestic dependent elementary or secondary school; or

(ii) The provision of a free public education to dependents of members of the Armed Forces residing on or near a military installation.

(2) Federal payments-in-lieu-of-taxes (PILOTs or PILTs), including PILTs for Federal entitlement lands authorized by Public Law 97–258, 31 U.S.C. §§ 6901–6906.

* * * * *

7. A new § 222.23 is added to read as follows:

§ 222.23 How does a local official determine the aggregate assessed value of eligible Federal property for the purpose of a local educational agency's section 8002 payment?

(a) The aggregate assessed value of eligible Federal property for the purpose of an LEA's section 8002 payment must be determined, by a local official responsible for assessing the value of real property located in the jurisdiction of the LEA for the purpose of levying a property tax, as follows:

(1) The local official first determines a fair market value (FMV) for the eligible Federal property in each Federal installation or other federally owned property (e.g., Federal forest), based on the highest and best use of taxable properties adjacent to the eligible Federal property.

(2) The local official then determines a section 8002 assessed value for each Federal installation or federally owned property by adjusting the FMV established in paragraph (a)(1) of this section by any percentage, ratio, index, or other factor that the official would use, if the eligible Federal property were taxable, to determine its assessed value for the purpose of generating local real property tax revenues for current expenditures. In making this adjustment, the official may assume that there was a transfer of ownership of the eligible Federal property for the year for which the section 8002 assessed value is being determined.

(3) The local assessor then calculates the aggregate section 8002 assessed value for all eligible Federal property in the LEA by adding the section 8002 assessed values for each different Federal installation or federally owned property determined in paragraph (a)(2) of this section.

Example: Two different Federal properties are located within a LEA—a Federal forest, and a naval facility. Based upon the highest and best use of taxable properties adjacent to the eligible Federal property, the local assessor establishes an FMV for the Federal forest of $1 million (woodland), and an FMV for the naval facility of $3 million (50 percent residential and 50 percent commercial/industrial). Assessed values in that taxing jurisdiction are determined by multiplying the FMV of property by an assessment ratio—the assessment ratio for woodland property is 30 percent of FMV, for residential 60 percent of FMV, and for commercial 75 percent of FMV.

To determine the section 8002 assessed value of the Federal forest, the assessor multiplies the FMV for that property ($1,000,000) by 30 percent (the assessment ratio for woodland property), resulting in a section 8002 assessed value of $300,000.

To determine the section 8002 assessed value for the naval facility, the assessor first must determine the portion of the total FMV attributable to each property type if that portion has not already been established. To make this determination for the residential portion, the assessor could multiply the total FMV ($3,000,000) for the naval facility by 50 percent (the portion of residential property), resulting in a $1.5 million FMV for the residential property. To determine a section 8002 assessed value for this residential portion, the assessor then would multiply the $1.5 million by 60 percent (assessment ratio for residential property), resulting in $900,000.

Similarly, to determine the portion of the FMV for the naval facility attributable to the commercial/industrial property, the assessor could multiply the total FMV ($3,000,000) by 50 percent (the portion of commercial/industrial property), resulting in $1.5 million. To determine the section 8002 assessed value for this commercial/industrial portion, the official then would multiply the $1.5 million by 75 percent (the assessment ratio for commercial/industrial property), resulting in $1,025,000. The assessor then must add the section 8002 assessed value figures for the residential portion ($900,000) and for the commercial/industrial portion ($1,025,000), resulting in a total section 8002 assessed value for the entire naval facility of $1,925,000.

Finally, the assessor determines the aggregate section 8002 assessed value for the LEA by adding the section 8002 assessed value for the Federal forest ($300,000), and the section 8002 assessed value for the naval facility ($1,925,000), resulting in an aggregate assessed value of $2,325,000.

(b) For the purpose of this section, the terms listed below have the following meanings:

(1) ''Adjacent'' means next to or close to the eligible Federal property. In most cases, this will be the closest taxable parcels.

(2)(i) ''Highest and best use'' of a parcel of adjacent property means the FMV of that parcel determined based upon a ''highest and best use'' standard in accordance with State or local law or guidelines if available. To the extent that State or local law or guidelines are not available, ''highest and best use'' generally will be a reasonable fair market value based upon the current use of those properties. However, the local official may also consider the most developed and profitable use for which the adjacent taxable property is physically adaptable and for which there is a need or demand for that use in the near future.

(ii) A local official may not base the ''highest and best use'' value of adjacent taxable property upon potential uses that are speculative or remote.

(iii) If the taxable properties adjacent to the eligible Federal property have different highest and best uses, these different uses must enter into the local official's determination of the FMV of the eligible Federal property under paragraph (a)(1) of this section.

Example: If a portion of a Federal installation to be valued has road or highway frontage with adjacent properties that are used for residential and commercial purposes, but the rest of the Federal installation is rural and vacant with adjacent properties that are agricultural, the local official must take into consideration the various uses of the adjacent properties (residential, commercial, and agricultural) in determining the FMV of the Federal property under paragraph (a)(1) of this section.

(Authority: 20 U.S.C. 7702)

8. New §§ 222.80 through 222.85 are added as subpart F (Payments to Local Educational Agencies for Children with Severe Disabilities under Section 8003(g) of the Act) to read as follows:

Subpart F—Payments to Local Educational Agencies for Children with Severe Disabilities under Section 8003(g) of the Act

222.80 What definitions apply to this subpart?
222.81 What requirements must a local educational agency meet to be eligible for a payment under section 8003(g) of the Act?
222.82 How does the Secretary calculate the total amount of funds available for payments under section 8003(g)?
222.83 How does an eligible local educational agency apply for a payment under section 8003(g)?
222.84 How does the Secretary calculate payments under section 8003(g) for eligible local educational agencies?
222.85 How may a local educational agency use funds that it receives under section 8003(g)?

Subpart F—Payments to Local Educational Agencies for Children with Severe Disabilities under Section 8003(g) of the Act

§ 222.80 What definitions apply to this subpart?

(a) The definitions in §§ 222.2 and 222.50 apply to this subpart.

(b) In addition, the following term applies to this subpart:

Children with severe disabilities means children with disabilities who because of the intensity of their physical, mental, or emotional problems, need highly specialized education, social, psychological, and medical services in order to maximize their full potential for useful and meaningful participation in society and for self-fulfillment. The term includes those children with disabilities with severe emotional disturbance (including schizophrenia), autism, severe and profound mental retardation, and those who have two or more serious disabilities such as deaf-blindness, mental retardation and blindness, and cerebral-palsy and deafness.

(Authority: 20 U.S.C. 1400 *et seq.*, 7703(g))

§ 222.81 What requirements must a local educational agency meet to be eligible for a payment under section 8003(g) of the Act?

An LEA is eligible for a payment under section 8003(g) of the Act if it—

(a) Is eligible for and receives a payment under section 8003(d) of the Act for children identified in paragraph (b) of this section and meets the requirements of §§ 222.52 and 222.83(b) and (c); and

(b) Incurs costs of providing a free appropriate public education to at least two children with severe disabilities whose educational program is being provided by an entity outside the schools of the LEA, and who each have a parent on active duty in the uniformed services.

(Authority: 20 U.S.C. 1221e–3, 1400 *et seq.*, 7703(a), (d), (g))

§ 222.82 How does the Secretary calculate the total amount of funds available for payments under section 8003(g)?

(a) In any fiscal year in which Federal funds other than funds available under the Act are provided to an LEA to meet the purposes of the Act, the Secretary—

(1) Calculates the sum of the amount of other Federal funds provided to an LEA to meet the purposes of the Act and the amount of the payment that the LEA

received for that fiscal year under section 8003(b) of the Act; and

(2) Determines whether the sum calculated under paragraph (a)(1) of this section exceeds the maximum basic support payment for which the LEA is eligible under section 8003(b), and, if so, subtracts from the amount of any payment received under section 8003(b), any amount in excess of the maximum basic support payment for which the LEA is eligible.

(b) The sum of all excess amounts determined in paragraph (a)(2) of this section is available for payments under section 8003(g) to eligible LEAs.

(Authority: 20 U.S.C. 7703(b), (g))

§ 222.83 How does an eligible local educational agency apply for a payment under section 8003(g)?

(a) In fiscal years in which funds are available for payments under section 8003(g), the Secretary provides notice to all potentially eligible LEAs that funds will be available.

(b) An LEA applies for a payment under section 8003(g) by submitting to the Secretary documentation detailing the total costs to the LEA of providing a free appropriate public education to the children identified in § 222.81, during the LEA's preceding fiscal year, including the following:

(1) For the costs of the outside entity providing the educational program for those children, copies of all invoices, vouchers, tuition contracts, and other similar documents showing the signature of an official or authorized employee of the outside entity; and

(2) For any additional costs (such as transportation) of the LEA related to providing an educational program for those children in an outside entity, copies of invoices, check receipts, contracts, and other similar documents showing the signature of an official or authorized employee of the LEA.

(c) An LEA applying for a payment must submit to the Secretary the information required under paragraph (b) of this section within 60 days of the date of the notice that funds will be available.

(Authority: 20 U.S.C. 1221e–3, 7703(g)(2))

§ 222.84 How does the Secretary calculate payments under section 8003(g) for eligible local educational agencies?

For any fiscal year in which the Secretary has determined, under § 222.82, that funds are available for payments under section 8003(g), the Secretary calculates payments to eligible LEAs under section 8003(g) as follows:

(a) For each eligible LEA, the Secretary subtracts an amount equal to that portion of the payment the LEA received under section 8003(d) of the Act for that fiscal year, attributable to children described in § 222.81, from the LEA's total costs of providing a free appropriate public education to those children, as submitted to the Secretary pursuant to § 222.83(b). The remainder is the amount that the LEA is eligible to receive under section 8003(g).

(b) If the total of the amounts for all eligible LEAs determined in paragraph (a) of this section is equal to or less than the amount of funds available for payment as determined in § 222.82, the Secretary provides each eligible LEA with the entire amount that it is eligible to receive, as determined in paragraph (a) of this section.

(c) If the total of the amounts for all eligible LEAs determined in paragraph (a) of this section exceeds the amount of funds available for payment as determined in § 222.82, the Secretary ratably reduces payments under section 8003(g) to eligible LEAs.

(d) If the total of the amounts for all eligible LEAs determined in paragraph (a) of this section is less than the amount of funds available for payment as determined in § 222.82, the Secretary pays the remaining amount to LEAs under section 8003(d). An LEA that receives such a payment shall use the funds for expenditures in accordance with the requirements of section 8003(d) and subpart D of these regulations.

(Authority: 20 U.S.C. 1221e–3, 7703(d) and (g))

§ 222.85 How may a local educational agency use funds that it receives under section 8003(g)?

An LEA that receives a payment under section 8003(g) shall use the funds for reimbursement of costs reported in the application that it submitted to the Secretary under § 222.83(b).

(Authority: 20 U.S.C. 7703(g)(2))

9. Section 222.95 is amended by revising the paragraph (g) introductory text to read as follows:

§ 222.95 How are Indian policies and procedures reviewed to ensure compliance with the requirements in section 8004(a) of the Act?

* * * * *

(g) An LEA that amends its IPPs shall, within 30 days, send a copy of the amended IPPs to—

* * * * *

10. New §§ 222.114 through 222.122 are added to subpart G, with a heading preceding them, to read as follows:

Withholding and Related Procedures for Indian Policies and Procedures

222.114 How does the Assistant Secretary implement the provisions of this subpart?
222.115 When does the Assistant Secretary withhold payments from a local educational agency under this subpart?
222.116 How are withholding procedures initiated under this subpart?
222.117 What procedures are followed after the Assistant Secretary issues a notice of intent to withhold payments?
222.118 How are withholding hearings conducted in this subpart?
222.119 What is the effect of withholding under this subpart?
222.120 When is a local educational agency exempt from withholding of payments?
222.121 How does the affected Indian tribe or tribes request that payments to a local educational agency not be withheld?
222.122 What procedures are followed if it is determined that the local educational agency's funds will not be withheld under this subpart?
222.123–222.129 [Reserved]

Withholding and Related Procedures for Indian Policies and Procedures

§ 222.114 How does the Assistant Secretary implement the provisions of this subpart?

The Assistant Secretary implements section 8004 of the Act and this subpart through such actions as the Assistant Secretary determines to be appropriate, including the withholding of funds in accordance with §§ 222.115–222.122, after affording the affected LEA, parents, and Indian tribe or tribes an opportunity to present their views.

(Authority: 20 U.S.C. 7704(d)(2), (e)(8)–(9))

§ 222.115 When does the Assistant Secretary withhold payments from a local educational agency under this subpart?

Except as provided in § 222.120, the Assistant Secretary withholds payments to an LEA if—

(a) The Assistant Secretary determines it is necessary to enforce the requirements of section 8004 of the Act or this subpart; or

(b) After a hearing has been conducted under section 8004(e) of the Act and §§ 222.102–222.113 (IPP hearing)—

(1) The LEA rejects the final determination of the Assistant Secretary; or

(2) The LEA fails to implement the required remedy within the time established and the Assistant Secretary determines that the required remedy will not be undertaken by the LEA even if the LEA is granted a reasonable extension of time.

(Authority: 20 U.S.C. 7704(a), (b), (d)(2), (e)(8)–(9))

§ 222.116 How are withholding procedures initiated under this subpart?

(a) If the Assistant Secretary decides to withhold an LEA's funds, the Assistant Secretary issues a written notice of intent to withhold the LEA's payments.

(b) In the written notice, the Assistant Secretary—

(1) Describes how the LEA failed to comply with the requirements at issue; and

(2)(i) Advises an LEA that has participated in an IPP hearing that it may request, in accordance with § 222.117(c), that its payments not be withheld; or

(ii) Advises an LEA that has not participated in an IPP hearing that it may request a withholding hearing in accordance with § 222.117(d).

(c) The Assistant Secretary sends a copy of the written notice of intent to withhold payments to the LEA and the affected Indian tribe or tribes by certified mail with return receipt requested.

(Authority: 20 U.S.C. 1221e–3(a)(1); 20 U.S.C. 7704(a), (b), (d)(2), and (e)(8)–(9))

§ 222.117 What procedures are followed after the Assistant Secretary issues a notice of intent to withhold payments?

(a) The withholding of payments authorized by section 8004 of the Act is conducted in accordance with section 8004(d)(2) or (e)(8)–(9) of the Act and the regulations in this subpart.

(b) An LEA that receives a notice of intent to withhold payments from the Assistant Secretary is not entitled to an Impact Aid hearing under the provisions of section 8011 of the Act and subpart J of these regulations.

(c) *After an IPP hearing.* (1) An LEA that rejects or fails to implement the final determination of the Assistant Secretary after an IPP hearing has 10 days from the date of the LEA's receipt of the written notice of intent to withhold funds to provide the Assistant Secretary with a written explanation and documentation in support of the reasons why its payments should not be withheld. The Assistant Secretary provides the affected Indian tribe or tribes with an opportunity to respond to the LEA's submission.

(2) If after reviewing an LEA's written explanation and supporting documentation, and any response from the Indian tribe or tribes, the Assistant Secretary determines to withhold an LEA's payments, the Assistant Secretary notifies the LEA and the affected Indian tribe or tribes of the withholding determination in writing by certified mail with return receipt requested prior to withholding the payments.

(3) In the withholding determination, the Assistant Secretary states the facts supporting the determination that the LEA failed to comply with the legal requirements at issue, and why the provisions of § 222.120 (provisions governing circumstances when an LEA is exempt from the withholding of payments) are inapplicable. This determination is the final decision of the Department.

(d) *An LEA that has not participated in an IPP hearing.*

(1) An LEA that has not participated in an IPP hearing has 30 days from the date of its receipt of the Assistant Secretary's notice of intent to withhold funds to file a written request for a withholding hearing with the Assistant Secretary. The written request for a withholding hearing must—

(i) Identify the issues of law and facts in dispute; and

(ii) State the LEA's position, together with the pertinent facts and reasons supporting that position.

(2) If the LEA's request for a withholding hearing is accepted, the Assistant Secretary sends written notification of acceptance to the LEA and the affected Indian tribe or tribes and forwards to the hearing examiner a copy of the Assistant Secretary's written notice, the LEA's request for a withholding hearing, and any other relevant documents.

(3) If the LEA's request for a withholding hearing is rejected, the Assistant Secretary notifies the LEA in writing that its request for a hearing has been rejected and provides the LEA with the reasons for the rejection.

(4) The Assistant Secretary rejects requests for withholding hearings that are not filed in accordance with the time for filing requirements described in paragraph (d)(1) of this section. An LEA that files a timely request for a withholding hearing, but fails to meet the other filing requirements set forth in paragraph (d)(1) of this section, has 30 days from the date of receipt of the Assistant Secretary's notification of rejection to submit an acceptable amended request for a withholding hearing.

(e) If an LEA fails to file a written explanation in accordance with paragraph (c) of this section, or a request for a withholding hearing or an amended request for a withholding hearing in accordance with paragraph (d) of this section, the Secretary proceeds to take appropriate administrative action to withhold funds without further notification to the LEA.

(Authority: 20 U.S.C. 1221e–3; 7704(a), (b), (d)(2), and (e)(8)–(9))

§ 222.118 How are withholding hearings conducted in this subpart?

(a) *Appointment of hearing examiner.* Upon receipt of a request for a withholding hearing that meets the requirements of § 222.117(d), the Assistant Secretary requests the appointment of a hearing examiner.

(b) *Time and place of the hearing.* Withholding hearings under this subpart are held at the offices of the Department in Washington, D.C., at a time fixed by the hearing examiner, unless the hearing examiner selects another place based upon the convenience of the parties.

(c) Proceeding. (1) The parties to the withholding hearing are the Assistant Secretary and the affected LEA. An affected Indian tribe is not a party, but, at the discretion of the hearing examiner, may participate in the hearing and present its views on the issues relevant to the withholding determination.

(2) The parties may introduce all relevant evidence on the issues stated in the LEA's request for withholding hearing or other issues determined by the hearing examiner during the proceeding. The Assistant Secretary's notice of intent to withhold, the LEA's request for a withholding hearing, and all amendments and exhibits to those documents, must be made part of the hearing record.

(3) Technical rules of evidence, including the Federal Rules of Evidence, do not apply to hearings conducted under this subpart, but the hearing examiner may apply rules designed to assure production of the most credible evidence available, including allowing the cross-examination of witnesses.

(4) Each party may examine all documents and other evidence offered or accepted for the record, and may have the opportunity to refute facts and arguments advanced on either side of the issues.

(5) A transcript must be made of the oral evidence unless the parties agree otherwise.

(6) Each party may be represented by counsel.

(7) The hearing examiner is bound by all applicable statutes and regulations and may neither waive them nor rule them invalid.

(d) *Filing requirements.* (1) All written submissions must be filed with the hearing examiner by hand-delivery, mail, or facsimile transmission. The Secretary discourages the use of facsimile transmission for documents longer than five pages.

(2) If agreed upon by the parties, a party may serve a document upon the other party by facsimile transmission.

(3) The filing date for a written submission under this subpart is the date the document is—

(i) Hand-delivered;

(ii) Mailed; or

(iii) Sent by facsimile transmission.

(4) A party filing by facsimile transmission is responsible for confirming that a complete and legible copy of the document was timely received by the hearing examiner.

(5) Any party filing a document by facsimile transmission must file a follow-up hard copy by hand-delivery or mail within a reasonable period of time.

(e) *Procedural rules.* (1) If the hearing examiner determines that no dispute exists as to a material fact or that the resolution of any disputes as to material facts would not be materially assisted by oral testimony, the hearing examiner shall afford each party an opportunity to present its case—

(i) In whole or in part in writing; or

(ii) In an informal conference after affording each party sufficient notice of the issues to be considered.

(2) With respect to withholding hearings involving a dispute as to a material fact the resolution of which would be materially assisted by oral testimony, the hearing examiner shall afford to each party—

(i) Sufficient notice of the issues to be considered at the hearing;

(ii) An opportunity to present witnesses on the party's behalf; and

(iii) An opportunity to cross-examine other witnesses either orally or through written interrogatories.

(f) *Decision of the hearing examiner.* (1) The hearing examiner—

(i) Makes written findings and an initial withholding decision based upon the hearing record; and

(ii) Forwards to the Secretary, and mails to each party and to the affected Indian tribe or tribes, a copy of the written findings and initial withholding decision.

(2) A hearing examiner's initial withholding decision constitutes the Secretary's final withholding decision without any further proceedings unless—

(i) Either party to the withholding hearing, within 30 days of the date of its receipt of the initial withholding decision, requests the Secretary to review the decision and that request is granted; or

(ii) The Secretary otherwise determines, within the time limits stated in paragraph (g)(2)(ii) of this section, to review the initial withholding decision.

(3) When an initial withholding decision becomes the Secretary's final decision without any further proceedings, the Department notifies the parties and the affected Indian tribe or tribes of the finality of the decision.

(g) *Administrative appeal of an initial decision.*

(1)(i) Any party may request the Secretary to review an initial withholding decision.

(ii) A party must file this request for review within 30 days of the party's receipt of the initial withholding decision.

(2) The Secretary may—

(i) Grant or deny a timely request for review of an initial withholding decision; or

(ii) Otherwise determine to review the decision, so long as that determination is made within 45 days of the date of receipt of the initial decision by the Secretary.

(3) The Secretary mails to each party and the affected Indian tribe or tribes, by certified mail with return receipt requested, written notice of—

(i) The Secretary's action granting or denying a request for review of an initial decision; or

(ii) The Secretary's determination to review an initial decision.

(h) *Secretary's review of an initial withholding decision.*

(1) When the Secretary reviews an initial withholding decision, the Secretary notifies each party and the affected Indian tribe or tribes in writing, by certified mail with return receipt requested, that it may file a written statement or comments; and

(2) Mails to each party and to the affected Indian tribe or tribes, by certified mail with return receipt requested, written notice of the Secretary's final withholding decision.

(Authority: 20 U.S.C. 7704)

§ 222.119 What is the effect of withholding under this subpart?

(a) The withholding provisions in this subpart apply to all payments that an LEA is otherwise eligible to receive under section 8003 of the Act for any fiscal year.

(b) The Assistant Secretary withholds funds after completion of any administrative proceedings under §§ 222.116–222.118 until the LEA documents either compliance or exemption from compliance with the requirements in section 8004 of the Act and this subpart.

(Authority: 20 U.S.C. 7704(a), (b), (d)(2), (e)(8)–(9))

§ 222.120 When is an LEA exempt from withholding of payments?

Except as provided in paragraph (d)(2) of this section, the Assistant Secretary does not withhold payments to an LEA under the following circumstances:

(a) The LEA documents that it has received a written statement from the affected Indian tribe or tribes that the LEA need not comply with section 8004 (a) and (b) of the Act, because the affected Indian tribe or tribes is satisfied with the provision of educational services by the LEA to the children claimed on the LEA's application for assistance under section 8003 of the Act.

(b) The Assistant Secretary receives from the affected Indian tribe or tribes a written request that meets the requirements of § 222.121 not to withhold payments from an LEA.

(c) The Assistant Secretary, on the basis of documentation provided by the LEA, determines that withholding payments during the course of the school year would substantially disrupt the educational programs of the LEA.

(d)(1) The affected Indian tribe or tribes elects to have educational services provided by the Bureau of Indian Affairs under section 1101(d) of the Education Amendments of 1978.

(2) For an LEA described in paragraph (d)(1) of this section, the Secretary recalculates the section 8003 payment that the LEA is otherwise eligible to receive to reflect the number of students who remain in attendance at the LEA.

(Authority: 20 U.S.C. 7703(a), 7704(c),(d)(2) and (e)(8))

§ 222.121 How does the affected Indian tribe or tribes request that payments to a local educational agency not be withheld?

(a) The affected Indian tribe or tribes may submit to the Assistant Secretary a formal request not to withhold payments from an LEA.

(b) The formal request must be in writing and signed by the tribal chairman or authorized designee.

(Authority: 20 U.S.C. 7704(d)(2) and (e)(8))

§ 222.122 What procedures are followed if it is determined that the local educational agency's funds will not be withheld under this subpart?

If the Secretary determines that an LEA's payments will not be withheld under this subpart, the Assistant Secretary notifies the LEA and the affected Indian tribe or tribes, in writing, by certified mail with return receipt requested, of the reasons why the payments will not be withheld.

(Authority: 20 U.S.C. 7704(d)–(e))

§ 222.150 [Amended]

11. In § 222.150, paragraph (b)(1) is amended by removing ''§§ 222.90–222.114'', and adding in its place ''§§ 222.90–222.122''.

12. Section 222.151 is amended by revising the title and paragraph (b)(1) to read as follows:

§ 222.151 When is an administrative hearing provided to a local educational agency?

* * * * *

(b) * * *

(1) The applicant files a written request for an administrative hearing within 30 days of its receipt of written notice of the adverse action; and

* * * * *

13. Section 222.152 is amended by revising paragraphs (b) and (c) to read as follows:

§ 222.152 When may a local educational agency request reconsideration of a determination?

* * * * *

(b) The Secretary's (or the Secretary's delegatee's) consideration of a request for reconsideration is not prejudiced by a pending request for an administrative hearing on the same matter, or the fact that a matter has been scheduled for a hearing. The Secretary (or the Secretary's delegatee) may, but is not required to, postpone the administrative hearing due to a request for reconsideration.

(c) The Secretary (or the Secretary's delegatee) may reconsider any determination under the Act or Pub. L. 81–874 concerning a particular party unless the determination has been the subject of an administrative hearing under this part with respect to that party.

(Authority: 20 U.S.C. 7711(a))

14. Section 222.154 is amended by revising paragraph (e) to read as follows:

§ 222.154 How must written submissions under this subpart be filed?

* * * * *

(e) Any party filing a document by facsimile transmission must file a follow-up hard copy by hand-delivery or mail within a reasonable period of time.

(Authority: 20 U.S.C. 7711(a))

§ 222.156 [Amended]

15. In § 222.156, paragraph (g) is amended by removing ''hearing examiner'', and adding in its place ''ALJ''.

16. Section 222.157 is amended by revising the title and paragraphs (a) and (b)(1) to read as follows:

§ 222.157 What procedures apply for issuing or appealing an administrative law judge's decision?

(a) *Decision.* (1) The ALJ—

(i) Makes written findings and an initial decision based upon the hearing record; and

(ii) Forwards to the Secretary, and mails to each party, a copy of the written findings and initial decision.

(2) An ALJ's initial decision constitutes the Secretary's final decision without any further proceedings unless—

(i) A party, within the time limits stated in paragraph (b)(1) of this section, requests the Secretary to review the decision and that request is granted; or

(ii) The Secretary otherwise determines, within the time limits stated in paragraph (b)(2)(ii) of this section, to review the initial decision.

(3) When an initial decision becomes the Secretary's final decision without any further proceedings, the Department's Office of Hearings and Appeals notifies the parties of the finality of the decision.

(b) *Administrative appeal of an initial decision.*

(1)(i) Any party may request the Secretary to review an initial decision.

(ii) A party must file such a request for review within 30 days of the party's receipt of the initial decision.

* * * * *

17. In § 222.158, the title, introductory language, and paragraph (b), are revised to read as follows:

§ 222.158 What procedures apply to the Secretary's review of an initial decision?

When the Secretary reviews an initial decision, the Secretary—

* * * * *

(b) Mails to each party written notice of the Secretary's final decision.

(Authority: 20 U.S.C. 7711(a))

18. In § 222.161, paragraph (c) is revised by removing the paragraph designations before each definition, reordering the definitions in alphabetical order, and adding in alphabetical order the following new definitions of ''Local tax revenues,'' ''Local tax revenues covered under a State equalization program,'' and ''Total local tax revenues'':

§ 222.161 How is State aid treated under section 8009 of the Act?

* * * * *

(c) *Definitions.* * * *

* * * * *

Local tax revenues means compulsory charges levied by an LEA or by an intermediate school district or other local governmental entity on behalf of an LEA for current expenditures for educational services. ''Local tax revenues'' include the proceeds of ad valorem taxes, sales and use taxes, income taxes and other taxes. Where a State funding formula requires a local contribution equivalent to a specified mill tax levy on taxable real or personal property or both, ''local tax revenues'' include any revenues recognized by the State as satisfying that local contribution requirement.

Local tax revenues covered under a State equalization program means ''local tax revenues'' as defined in paragraph (c) of this section contributed to or taken into consideration in a State aid program subject to a determination under this subpart, but excluding all revenues from State and Federal sources.

* * * * *

Total local tax revenues means all ''local tax revenues'' as defined in paragraph (c) of this section, including revenues for education programs for children needing special services, vocational education, transportation, and the like during the period in question but excluding all revenues from State and Federal sources.

* * * * *

19. In § 222.164, paragraphs (a)(2) and (b) are revised to read as follows:

§ 222.164 What procedures does the Secretary follow in making a determination under section

8009? (a) * * *

(2) Whenever a proceeding under this subpart is initiated, the party initiating the proceeding shall give adequate notice to the State and all LEAs in the State and provide them with a complete copy of the submission initiating the proceeding. In addition, the party initiating the proceeding shall notify the State and all LEAs in the State of their right to request from the Secretary, within 30 days of the initiation of a proceeding, the opportunity to present their views to the Secretary before the Secretary makes a determination.

(b) *Submission.* (1) A submission by a State or LEA under this section must be made in the manner requested by the Secretary and must contain the information and assurances as may be required by the Secretary in order to reach a determination under section 8009 and this subpart.

(2)(i) A State in a submission shall—

(A) Demonstrate how its State aid program comports with § 222.162; and

(B) Demonstrate for each LEA receiving funds under the Act that the proportion of those funds that will be taken into consideration comports with § 222.163.

(ii) The submission must be received by the Secretary no later than 120 calendar days before the beginning of the State's fiscal year for the year of the

determination, and must include (except as provided in § 222.161(c)(2)) final second preceding fiscal year disparity data enabling the Secretary to determine whether the standard in § 222.162 has been met. The submission is considered timely if received by the Secretary on or before the filing deadline or if it bears a U.S. Postal Service postmark dated on or before the filing deadline.

(3) An LEA in a submission must demonstrate whether the State aid program comports with section 8009.

(4) Whenever a proceeding is initiated under this subpart, the Secretary may request from a State the data deemed necessary to make a determination. A failure on the part of a State to comply with that request within a reasonable period of time results in a summary determination by the Secretary that the State aid program of that State does not comport with the regulations in this subpart.

(5) Before making a determination under section 8009, the Secretary affords the State, and all LEAs in the State, an opportunity to present their views as follows:

(i) Upon receipt of a timely request for a predetermination hearing, the Secretary notifies all LEAs and the State of the time and place of the predetermination hearing.

(ii) Predetermination hearings are informal and any LEA and the State may participate whether or not they requested the predetermination hearing.

(iii) At the conclusion of the predetermination hearing, the Secretary holds the record open for 15 days for the submission of post-hearing comments. The Secretary may extend the period for post-hearing comments for good cause for up to an additional 15 days.

(iv) Instead of a predetermination hearing, if the party or parties requesting the predetermination hearing agree, they may present their views to the Secretary exclusively in writing. In such a case, the Secretary notifies all LEAs and the State that this alternative procedure is being followed and that they have up to 30 days from the date of the notice in which to submit their views in writing. Any LEA or the State may submit its views in writing within the specified time, regardless of whether it requested the opportunity to present its views.

* * * * *

(Authority: 20 U.S.C. 7709)

20. In § 222.165, paragraphs (e), (f), and (h) are revised to read as follows:

§ 222.165 What procedures does the Secretary follow after making a determination under section 8009?

* * * * *

(e) *Proceedings.* (1) The Secretary refers the matter in controversy to an administrative law judge (ALJ) appointed under 5 U.S.C. 3105.

(2) The ALJ is bound by all applicable statutes and regulations and may neither waive them nor rule them invalid.

(f) *Filing requirements.* (1) Any written submission under this section must be filed by hand-delivery, mail, or facsimile transmission. The Secretary discourages the use of facsimile transmission for documents longer than five pages.

(2) If agreed upon by the parties, service of a document may be made upon the other party by facsimile transmission.

(3) The filing date for a written submission under this section is the date the document is—

(i) Hand-delivered;

(ii) Mailed; or

(iii) Sent by facsimile transmission.

(4) A party filing by facsimile transmission is responsible for confirming that a complete and legible copy of the document was received by the Department.

(5) Any party filing a document by facsimile transmission must file a follow-up hard copy by hand-delivery or mail within a reasonable period of time.

* * * * *

(h) *Decisions.* (1) The ALJ—

(i) Makes written findings and an initial decision based upon the hearing record; and

(ii) Forwards to the Secretary, and mails to each party, a copy of the written findings and initial decision.

(2) Appeals to the Secretary and the finality of initial decisions under section 8009 are governed by §§ 222.157(b), 222.158 and 222.159 of subpart J.

(Authority: 20 U.S.C. 7709)

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Monday
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Part V

Environmental Protection Agency

Effluent Guidelines Plan; Notice

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5617–7]

RIN 2040–AC86

Effluent Guidelines Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of effluent guidelines plan.

SUMMARY: Today's notice announces the Agency's plans for developing new and revised effluent guidelines, which regulate industrial discharges to surface waters and to publicly owned treatment works. Section 304(m) of the Clean Water Act requires EPA to publish a biennial Effluent Guidelines Plan.

EFFECTIVE DATE: November 6, 1996.

ADDRESSES: The public record for this notice is available for review in the EPA Water Docket, 401 M Street, SW., Washington, DC. For access to Docket materials, call (202) 260–3027 between 9 a.m. and 3 p.m. for an appointment. The EPA public information regulation (40 CFR Part 2) provides that a reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Eric Strassler, Engineering and Analysis Division (4303), Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460; telephone 202–260–7150.

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I. Regulated Entities

Today's proposed plan does not contain regulatory requirements and does not provide specific definitions for each industrial category. Entities potentially affected by decisions regarding the final plan are listed below.

Category of entity	Examples of potentially affected entities
Industry	Pulp, Paper and Paperboard; Pesticide Formulating, Packaging and Repackaging; Coastal Oil and Gas Extraction; Centralized Waste Treatment; Pharmaceutical Manufacturing; Metal Products and Machinery; Landfills and Incinerators; Industrial Laundries; Transportation Equipment Cleaning; Iron and Steel Manufacturing; Chemical Formulators, Packagers and Repackagers; Feedlots; Inorganic Chemicals; Petroleum Refining; Photographic Processing; Steam Electric Power Generating; Storm Water dischargers; Textile Mills.

To determine whether your facility would be regulated, you should carefully examine the applicability criteria in the appropriate proposed rule (previously published or forthcoming). Citations for previously published proposed rules and schedules for forthcoming proposed rules are provided in Appendix A of today's notice.

II. Legal Authority

Today's notice is published under the authority of section 304(m) of the Clean Water Act, 33 U.S.C. 1314(m).

III. Introduction

A. Purpose of Today's Notice

Today's notice announces the Agency's third biennial plan for developing new and revised effluent guidelines pursuant to sec. 304(m) of the Clean Water Act.

EPA published a proposed Effluent Guidelines Plan (the ''Proposed Plan'') on July 3, 1996 (61 FR 35042). The Agency accepted comment on the notice until August 9, 1996. Today's notice summarizes and addresses the major comments the Agency received.

B. Overview of Today's Notice

The Agency intends to develop effluent limitation guidelines and standards (''effluent guidelines'') as follows:

1. Continue development of ten rules listed in the Proposed Plan. The categories are: Pulp, Paper and Paperboard; Pesticide Chemicals (Formulating, Packaging and Repackaging); Coastal Oil and Gas Extraction; Centralized Waste Treatment; Pharmaceutical Manufacturing; Metal Products and Machinery, Phase 1; Landfills and Incinerators; Industrial Laundries; Transportation Equipment Cleaning; and Metal Products and Machinery, Phase 2.

2. Begin development of revised effluent guidelines for the Iron and Steel Manufacturing category.

3. Initiate three preliminary studies to assist in determining whether new or revised rules should be developed for particular categories. Each preliminary study will generally take approximately two years to complete.

4. Complete preliminary studies on the Photographic Processing and Chemical Formulating and Packaging industries.

5. Plan for development of seven additional effluent guidelines, either new or revised. The point source categories to be covered by these guidelines will be identified in future biennial Effluent Guidelines Plans.

These actions are identical to those described in the Proposed Plan.

IV. 1996 Proposed Effluent Guidelines Plan

In the Proposed Plan, EPA described its intent to continue development of ongoing rulemakings, develop additional rules, and conduct preliminary studies. The Proposed Plan set forth EPA's rationale for the selection of particular industries as candidates for new or revised effluent guidelines. The Proposed Plan also described the relevant statutory framework, the components and process for development of an effluent guidelines regulation, and other background information. The principal elements of the Proposed Plan were designed to implement sec. 304(m) and a consent decree in *Natural Resources Defense Council et al* v. *Browner* (D.D.C. 89–2980, January 31, 1992, as modified) (the ''Consent Decree''). See 61 FR 35042–35052.

V. 1996 Effluent Guidelines Plan

EPA's 1996 Effluent Guidelines Plan is set forth below. Today's Plan is substantively identical to the Proposed Plan. As noted above, the basis for selection of the industries identified in today's Plan is described in the Proposed Plan.

A. Regulations

1. Ongoing Rulemakings

The Agency is currently in the process of developing new or revised effluent guidelines for ten categories. (These categories were listed in the Proposed Plan.) The categories and actual or projected dates for proposal and final action are set forth in Table 1.

TABLE 1.—EFFLUENT GUIDELINES CURRENTLY UNDER DEVELOPMENT

Category	Proposal	Final action
	Consent decree or actual	Consent Decree
Pulp, Paper and Paperboard	12/17/93	([1])
Pesticide Formulating, Packaging, and Repackaging	4/14/94	9/96
Centralized Waste Treatment	1/27/95	[2] 3/97
Coastal Oil and Gas Extraction	2/17/95	10/96
Pharmaceutical Manufacturing	5/2/95	[2] 3/97
Metal Products and Machinery, Phase 1	5/30/95	[2 4] 3/97
Industrial Laundries	[2] 3/97	[3] 12/98
Transportation Equipment Cleaning	[2] 3/97	[3] 12/98
Landfills and Incinerators	[3] 3/97	[3] 3/99
Metal Products and Machinery, Phase 2	[3 4] 12/97	[3 4] 12/99

[1] The Pulp, Paper and Paperboard rulemaking is not covered by the January 31, 1992 consent decree.
[2] 3/97 is an interim deadline by which EPA and NRDC expect to conclude negotiations. EPA may not propose or promulgate these rules by 3/97.
[3] EPA is discussing extensions to Consent Decree dates with NRDC.
[4] EPA is considering merging Phases 1 and 2 of the Metal Products and Machinery rule.

The Agency has not yet received funding for Fiscal Year 1997, and funding restrictions may affect rulemaking schedules. EPA is discussing extensions to most of the Consent Decree dates with NRDC, for both budgetary reasons and specific policy, technical and administrative issues in some regulations.

2. Future Regulations

a. *Iron and Steel Manufacturing.* As announced in the Proposed Plan, EPA intends to propose revised regulations for the Iron and Steel Manufacturing Category. The current consent decree deadlines are December 1998 for proposal and December 2000 for promulgation; however, EPA is discussing extensions to these deadlines with NRDC.

b. Additional Rulemaking Projects. The Decree currently requires that EPA develop seven additional rules. Based on the discussion of data sources in the Proposed Plan (61 FR 35047), the Agency may choose the next rulemaking projects from the following list of categories:

- Chemical Formulators, Packagers and Repackagers.
- Feedlots.
- Inorganic Chemicals.
- Petroleum Refining.
- Photographic Processing.
- Steam Electric Power Generating.
- Storm Water.
- Textile Mills.

Completed, ongoing or potential preliminary studies on these categories were discussed in the Proposed Plan (61 FR 35047–35051). The Agency may consider other categories for rulemaking as it receives additional data. The Consent Decree deadlines for the additional rules are part of the Agency's ongoing negotiations with NRDC.

B. Preliminary Studies

In the Proposed Plan EPA described preliminary studies either completed or underway, and announced that it intended to begin additional preliminary studies. The studies assist the Agency in selecting industries to be subject to future effluent guidelines rulemaking.

The Agency is completing work on two studies: Photographic Processing and Chemical Formulating, Packaging and Repackaging. EPA will begin additional studies, but has not yet selected the categories for study.

C. Summary of Changes From Proposed Plan

Today's Effluent Guidelines Plan is substantively identical to the Proposed Plan. However, some clarifications are provided below in response to several comments the Agency received on the proposal.

D. Updates on Rulemaking Activities

1. Pulp, Paper and Paperboard

On July 15, 1996, EPA published a notice of data availability (61 FR 36835) that described the Agency's goals for environmental improvement in the pulp, paper, and paperboard industry. This notice also announced the availability of new data related to the proposed effluent limitation guidelines and standards and discussed the preliminary results of detailed analysis relative to a portion of this industry. Finally, this notice discussed an innovative new approach to foster continuing environmental improvement through the development and use of a voluntary incentives-based program for implementing advanced pollution prevention technologies that move the industry closer to meeting the Clean Water Act goal of zero discharge.

2. Centralized Waste Treatment

EPA published a Notice of Availability on September 16, 1996 (61 FR 48805). The notice describes new information the Agency has obtained since the proposed rule of January 27, 1995. The notice also explains, based on this information, the Agency's revised estimates of the size and regulatory impacts of the proposed rulemaking on the proposed oils treatment and recovery subcategory.

3. Leather Tanning and Finishing

EPA issued a direct final rule concerning minor revisions to the Leather Tanning and Finishing regulations (40 CFR Part 425) on July 8, 1996 (61 FR 35680). These revisions

will become effective on October 6, 1996.

4. Ore Mining and Dressing

EPA proposed modifications to the Copper, Lead, Zinc, Gold, Silver and Molybdenum subcategory of the Ore Mining regulations (40 CFR part 440, Subpart J) on February 12, 1996 (61 FR 5364). The proposed modifications involved an exemption from a requirement for a mine to use impoundments or ''tailings ponds'' where such requirements would be impractical due to severe topographic and climatic conditions. Such conditions appear to exist at the Alaska-Juneau (A–J) gold mine project near Juneau, Alaska. The public comment period for comments concerning technological alternatives for the A–J project site closed on August 12, 1996. EPA is reviewing the comments and evaluating alternatives as part of the Region 10 Supplemental Environmental Impact Statement (SEIS). The Agency will publish a notice announcing the additional data and is scheduling a series of public meetings for late October or early November 1996. These meetings will be announced in the Federal Register.

VI. Public Comments

EPA accepted public comment on the Proposed Plan until August 9, 1996. The Agency received comments that covered approximately 30 topics from 48 commenters, including industries, an environmental group, States, publicly owned treatment works, and Federal agencies. The summary in this section highlights the significant comments submitted. The administrative record for today's notice includes a complete text of the comments and the Agency's responses.

A. Scope of Specific Effluent Guidelines Rules

Several comments addressed the scope of coverage and other issues pertaining to specific effluent guidelines rules which EPA recently proposed or will propose in the next few years.

EPA will forward these comments to the dockets for the appropriate rules. The Agency has not made final decisions about the scope and applicability of these guidelines.

B. Metal Products and Machinery

In the Proposed Plan, EPA stated that it was considering merging Phases 1 and 2 of the Metal Products and Machinery (MP&M) rule (61 FR 35045). Eighteen commenters supported EPA's proposal to merge Phases 1 and 2 of the MP&M rulemaking into one final rule. EPA will consider these recommendations as it continues to negotiate extensions of the Consent Decree deadlines for the MP&M rules with NRDC.

C. Pharmaceutical Manufacturing

In the Proposed Plan, EPA stated that it was considering the merits of jointly promulgating effluent guidelines along with planned National Emission Standards for Hazardous Air Pollutants (NESHAP) regulations for the pharmaceutical industry (61 FR 35046). Eleven commenters supported simultaneous promulgation of air and water standards for the Pharmaceuticals industry. EPA will consider these recommendations as it continues to negotiate an extension of the Consent Decree deadline for the Pharmaceuticals effluent guidelines rule with NRDC.

D. Preliminary Studies

Several comments supported or opposed EPA's conducting preliminary studies of certain categories, and some of the commenters also recommended issues to be considered if the studies were conducted. The Agency has not selected categories for studies. As studies are selected, EPA will consider the issues raised by the commenters.

E. Industry Selection Criteria

In the Proposed Plan, EPA described its process for selection of new effluent guidelines (61 FR 35046). In discussing the Agency's use of various factors in comparing industrial categories, one commenter recommended that the Agency's use of ''total pollutants discharged'' information should be adapted in recognition of significant changes in influent loadings to publicly owned treatment works (POTWs) as the result of implementation of local pretreatment programs and changes in analytical techniques. EPA agrees that load estimates should reflect local pretreatment programs and current conditions. However, the Agency generally cannot obtain category-wide data on pretreatment of industrial loadings during the selection process. In addition to its quantitative estimates, EPA does make qualitative evaluations about the relative extent of POTW local limits for different industrial categories during the selection process.

Another commenter recommended that in the environmental factors, EPA should consider the availability of treatment technologies that may result in significant reductions of existing pollutants; discontinue use of ''total pollutants discharged''; compare industry discharges on a facility basis, not total industry basis, and look at pollutant concentrations; use NPDES permit application data for comparisons; and evaluate effects of other EPA regulations on effluent quality. EPA does consider the availability of treatment technologies as well as relative costs. In the Proposed Plan (61 FR 35046), the discussion on the ''Utility'' criterion stated that ''EPA typically looks at a variety of factors'', however only several of these factors were listed for brevity: Average priority pollutants discharged per facility, Average priority toxic pounds-equivalent discharged per facility, and Number of discharging facilities. The other factors the Agency considers under the ''Utility'' criterion are: Potential For Additional Control, Pollution Prevention Opportunity, Multi-Media Rule Opportunity, Extent of Industry Not Covered by Existing Effluent Guidelines, Variability of Industry Discharges, Inapplicability of Existing Regulations, and Potential Impact of Indirect Dischargers. For some of these factors, EPA may not have quantitative data, and the Agency relies on the engineering judgment of its professional staff.

EPA uses total pollutant discharge to evaluate an industry's overall impact on the nation's waters. Additionally, EPA does examine average discharge per facility. EPA considers pollutant loads rather than pollutant concentrations in order to evaluate potential impact to the environment (e.g. sediment loadings and bioaccumulation potential). EPA uses the NPDES Permit Compliance System (PCS), which includes self-monitoring data, to estimate loads. Resource limitations preclude the Agency from reviewing individual permit applications. EPA agrees that estimating impacts on wastewater discharges from non-water environmental regulations is important, and will attempt to calculate these impacts where data are available. Typically, after implementation of a final rule, there is a delay of perhaps several years before wastewater impacts can be estimated for a category.

A third commenter stated that among the environmental factors, a description of contact path and associated risk should be included, e.g. bioaccumulation in food chain to levels much greater than originally in the receiving water. EPA agrees that the exposure route is an important criterion but the Agency does not have the resources to evaluate each chemical discharged for all industries. However, EPA does consider the relative risk of pollutant discharge by using the criteria toxic pound equivalence. Toxic pound equivalence allows comparison of the relative toxicity of pollutants in terms of

human health and aquatic life protection. This criterion also accounts for the bioaccumulation potential of pollutants.

VII. Economic Impact Assessment

Today's notice proposes a plan for the review and revision of existing effluent guidelines and for the selection of priority industries for new regulations. This notice does not establish any requirements; therefore, no economic impact assessment has been prepared. EPA will provide economic impact analyses or regulatory impact analyses, as appropriate, for all of the future effluent guideline rulemakings developed by the Agency.

VIII. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines ''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 entitlements, 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 that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

Dated: September 27, 1996.

Carol M. Browner,

Administrator.

Appendix A—Effluent Guidelines Rulemaking Projects and Preliminary Studies

Effluent Guidelines Current and Future Rulemaking Projects

Category	40 CFR part	Proposed	Final
Pulp, Paper and Paperboard	430	12/17/93 (58 FR 66078)	([1])
Pesticide Formulating, Packaging and Repackaging	455	4/14/94 (59 FR 17850)	9/96
Centralized Waste Treatment	437	1/27/95 (60 FR 5464)	[2] 3/97
Coastal Oil and Gas Extraction	435	2/17/95 (60 FR 9428)	10/96
Pharmaceutical Manufacturing	439	5/2/95 (60 FR 21592)	[2] 3/97
Metal Products and Machinery, Phase 1	438	5/30/95 (60 FR 28209)	[2, 4] 3/97
Industrial Laundries	441	3/97 [2]	[3] 12/98
Transportation Equipment Cleaning	442	3/97 [2]	[3] 12/98
Landfills and Incinerators	437	3/97 [3]	[3] 3/99
Metal Products and Machinery, Phase 2	438	12/97 [3, 4]	[3, 4] 12/99
Iron and Steel Manufacturing	420	12/98 [3]	[3] 12/00
1 category		12/98 [3]	[3] 12/00
2 categories		12/99 [3]	[3] 12/01
2 categories		12/00 [3]	[3] 12/02
2 categories		12/01 [3]	[3] 12/03

Notes

[1] The Pulp, Paper and Paperboard rulemaking is not covered by the January 31, 1992 consent decree.

[2] 3/97 is an interim deadline by which EPA and NRDC expect to conclude negotiations. EPA may not propose or promulgate these rules by 3/97.

[3] EPA is discussing extensions to Consent Decree dates with NRDC.

[4] EPA is considering merging Phases 1 and 2 of the Metal Products and Machinery rule.

Current and Future Preliminary Studies

Category	Complete
Petroleum Refining	1993
Metal Finishing	1993
Textile Mills	1994
Inorganic Chemicals	1994
Steam Electric Power Generating	1995

Current and Future Preliminary Studies—Continued

Category	Complete
Iron and Steel Manufacturing	1995
Photographic Processing	1996
Chemical Formulators and Packagers [1] 1996.	

Current and Future Preliminary Studies—Continued

Category	Complete
Three studies [1] 1997.	

Note

[1] EPA is discussing extensions to Consent Decree dates with NRDC.

[FR Doc. 96–25653 Filed 10–4–96; 8:45 am]

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Monday
October 7, 1996

Part VI

Environmental Protection Agency

Facility Identification Initiative; Notice

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS–00186; FRL–4991–5]

RIN 2070–AC92

Facility Identification Initiative

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice and Request for Comments.

SUMMARY: As part of EPA's effort to reinvent environmental regulations the Agency is seeking comment on a number of options to standardize facility data reporting. This initiative represents the first step of a larger Agency effort to streamline and consolidate EPA's collection and maintenance of environmental data. Specifically, in this Notice EPA is considering options for establishing a national standard for the reporting and maintenance of information regarding the identification of facilities that are subject to federal environmental reporting and permitting requirements. EPA believes that a successful standardized facility identification scheme would reduce reporting burden on the regulated community while improving public access to the Agency's environmental data. Since States are partners with EPA in receiving and managing environmental data, EPA has actively sought the participation of State representatives during the development of this Initiative. This Notice is intended to provide all stakeholders with an opportunity to comment on the goals and benefits of the Facility Identification Initiative, as well as on the potential approaches for implementation.

DATES: Written comments on this Notice must be received by EPA on or before December 23, 1996.

ADDRESSES: Written comments should be submitted in triplicate to: TSCA Document Receipt Office, (7407), Environmental Protection Agency, Office of Pollution Prevention and Toxics, 401 M St., SW., Washington, DC 20460. Comments should include the document control number for this Notice, OPPTS–00186.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: oppt.ncic@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number OPPTS–00186. Comments containing Confidential Business Information (CBI) should be submitted to the same address, with all CBI clearly identified, and must include a sanitized copy for the public record. No CBI should be submitted through e-mail. Electronic comments on this Notice may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: Sam K. Sasnett or Mary C. Hanley, Project Managers, 202-260-8020 or 202-260-1624, Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-108, Mail Code 7407, 401 M St., SW., Washington, DC 20460; e-mail: sasnett.sam@epamail.epa.gov, or hanley.mary@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

The EPA and its governmental regulatory partners are authorized to collect a wide range of data from a variety of sources. For example, the data may be related to the management of wastes, to the maintenance of operations at a particular location in accordance with a permit, or to the locations at which pesticides are formulated. For the most part, the Federal laws authorizing environmental data collections were developed under different statutory authorities to address specific environmental media concerns such as hazardous and toxic chemical emissions and spills, control of pesticide use, air pollution, surface and subsurface water contamination, the management of solid and hazardous waste, the delivery of safe drinking water, and the cleanup of existing waste deposits. EPA, State, and local governments developed organizational structures and programs tailored to address these specific, single-media concerns. Consequently, the collection, maintenance, and use of environmental data by EPA and the States follow this media-by-media approach to addressing environmental concerns.

In more recent years, concepts of environmental protection have evolved toward cross-media environmental impacts, the need to prevent pollution at the source, and the importance of a well-informed public participating in the decision making process. In most cases, however, environmental data collection and management has not adjusted to this evolution and is still collected and maintained in a media-specific way.

Compounding this situation is the growing need for both government and the private sector to cut costs and increase the efficiency of operations. Currently, industries must report environmental information to many different offices, at different times, and in different formats. At the same time, the public expects to have access to accurate, comprehensive environmental data. Together, these forces are stimulating a fundamental and inevitable change in the collection and management of environmental data.

Therefore, the Facility Identification Initiative represents a significant Agency reinvention commitment. The Initiative is a first step toward establishing a new one-stop reporting approach for environmental data. By having facilities identified the same way for all reporting requirements under environmental laws, a new approach can be established which will simplify reporting for affected parties and simplify public access to information currently residing in many different places. The President announced this initiative in the March 1995 report, *Reinventing Environmental Regulation*. EPA will work closely with states to design this new approach. Facility identification is an important building block in this critical reinvention initiative.

EPA believes that there is already a broad base of support for this initiative. For example, in August 1994, the National Advisory Council for Environmental Policy and Technology (NACEPT) published a report entitled ''Using Information Strategically to Protect Human Health and the Environment: Recommendations for Comprehensive Information Resources Management'' (Ref. 1). This report was developed by NACEPT's Information Resources Management Strategic Planning Task Force, which involved representatives of all the major groups concerned with EPA policy, including industry, states and local governments, the environmental community, and other government agencies. The NACEPT Committee made four major recommendations:

(1) EPA must use information strategically to achieve the Agency's mission.

(2) EPA must actively use information to empower its partners.

(3) EPA must establish an integrated information infrastructure to support a comprehensive approach to environmental protection.

(4) EPA must establish a more effective organization for information resources management.

Under the third recommendation, the Committee went on to state that:

Data standardization is a fundamental part of EPA's integrated information infrastructure. The first step towards standardizing data is to identify those common data elements widely used throughout the Agency and by State Co-Implementors, which provide the framework to link and combine information.

Without standardized facility data across environmental data collections, two major problems persist. First, lack of standardized facility identification data makes it difficult to establish a linkage between all environmental data relating to the same facility. Second, multiple reporting of facility-specific data results in inefficiencies and additional burden for both the regulated community and regulators, and impedes public right-to-know.

A primary problem that users of EPA and State environmental data experience is the difficulty (and in some cases the inability) to establish reliable links between data relating to the same facility. There are several underlying factors. There are inconsistencies in the facility identification data. A slightly different spelling of a facility name or address reduces the accuracy and effectiveness of comparing the data about a facility. Also, different reporting requirements may have different statutory or regulatory definitions for the reporting facility. This can result in reports that may represent the same facility but that appear to be different.

There are numerous, separate environmental data collections that include the reporting of different facility identification data. The submitter must repeatedly report such data to multiple EPA and State data systems and the Agencies must also separately input and maintain such identification data. Developing some means to consolidate such reporting could lead to greater efficiencies for both the regulated community and government agencies that receive and maintain such data. Finally, it could improve the accuracy of the data and provide the public with easier access to the data.

The Agency believes that these data linkage problems and reporting inefficiencies could be alleviated by developing a universal set of facility identification data which is shared by EPA and the States. Standardizing facility identification data could also pave the way for any further consolidation of Federal environmental data. Therefore, this Notice represents a detailed outline of the Agency's concepts on facility data standardization and consolidation.

B. Goals of the Facility Identification Initiative

The overarching goal of the Facility Identification Initiative is:

To streamline access to and reporting of environmental data by establishing a uniform set of facility identification data and the infrastructure needed to make it operational.

The specific objectives of the initiative are:

(1) To obtain and maintain an accurate set of uniform, facility-specific information and keep it current.

(2) To build an infrastructure based upon as many existing approaches as possible that efficiently support data linkage capabilities.

(3) To improve public access to Agency data, to empower communities and to support multi-media analysis of environmental issues.

(4) To minimize the burden on the regulated community and States as part of the process of obtaining and maintaining such information, and eliminate, where possible, duplication.

(5) To serve as a first practical step toward the broader goal of consolidating environmental data collection.

C. Benefits of the Facility Identification Initiative

The Facility Identification Initiative is seeking to create two features that will work together to create an electronic pointer system to Agency data. The first feature is a single record of consistent facility identification data (e.g. facility name, street address, corporate affiliation, etc.) established and updated for each reporting facility. The second feature is a unique facility identification number which is assigned to each facility. The facility identification number would then serve as the primary link or electronic pointer to all of the Agency's data about that facility.

EPA believes that there are numerous benefits of establishing a universal set of facility identification data to be shared between EPA, States and the public.

1. *Better access to data by facility*. For the first time, reliable links will be established between data relating to the same facility held in separate EPA and State data systems. Standardization of facility identification data will eliminate inconsistencies in facility identification data that currently exist. Environmental data about a facility can be found and used more effectively.

2. *Improved access by the public*. The public would be provided with improved access to the Agency's environmental data. The facility identification data will provide new and greater capabilities for the public to access Federal environmental data, and allow for links to other data sources.

Providers of information can also use the facility identification data as a tool to locate and check the accuracy of their data as represented in EPA and/or other systems. Standard facility identification data could increase opportunities for the owners or operators of facilities to tell their own story about site-specific or corporate pollution prevention and environmental progress. For example, the data could be designed to allow a facility to provide an Internet address as well as an E-mail address. This could serve as a link to further information, analyses, reports, or interpretations that the data provider believes would enable the public to better understand its submissions.

3. *Improve multi-media perspectives*. The facility identification data would better support the efforts of data users who want to compile or analyze environmental data across media data collections. In particular, it would support those doing geographic or community-based analyses. Having an up-to-date linkage capability could significantly increase the reliability of multi-media analyses by providing a standard framework for organizing and storing facility information.

4. *Empowering communities*. Facility identification data can serve as a tool to empower communities by aiding them in identifying the presence of detailed environmental data related to a specific facility within their localities.

5. *Reducing burden*. Consolidating facility identification data could lead the way, over time, to reduce the reporting burden for those required to submit data under a number of existing Federal environmental regulations. The facility identification data of the individual reporting forms could be abbreviated. EPA is mindful of the need to implement the facility identification initiative creatively and in a fashion that minimizes burden on the regulated community. Thus, no additional burden will be placed on the regulated communities to reconcile facility data that EPA has already collected. The Agency will do an initial reconciliation of facility data using existing records, without asking facilities to submit additional information. Facilities would be provided an opportunity to voluntarily review and verify (electronically) their reconciled facility record if they choose to do so. Care also needs to be taken to minimize burden on the regulated community when deciding which data elements to consolidate into a single facility record. For example, EPA is considering innovative ways to include latitude-

longitude coordinates in the consolidated facility record without requiring facilities to incur any new reporting burden. Rather than requiring that facilities report longitude and latitude data, EPA intends to use secondary sources to populate these data fields. EPA will expend its own resources to conduct address matching and will use existing sources such as State data, to ascertain longitude and latitude for each facility. EPA is also considering providing Federal and State inspectors with the means to ascertain longitude and latitude easily and uniformly, or perhaps empowering facilities themselves with the means to do so voluntarily. One of EPA's primary objectives is not only to avoid imposing any new burden, but to also reduce existing burden wherever possible. As such, EPA is very interested in receiving comments or suggestions on ways that EPA can implement a consolidation program and still achieve either a zero impact on burden or a net reduction.

II. Approaches to Achieving Facility Identification

This unit explores a number of alternatives for implementing the Facility Identification Initiative. Each alternative addresses who (e.g. EPA, the State, the facility) takes responsibility for data reconciliation, keeping the facility data record current, and providing public access. In reviewing these discussions, EPA requests that the reader consider how any individual alternative supports or does not support one or more of the goals as outlined in Unit I.B. of this document. Also, EPA requests reviewers to comment on the practical feasibility and relative probability of success of a given approach. The approaches are not mutually exclusive of each other, so the reader might comment that one or more approaches should be combined. Additionally, EPA also encourages commenters to suggest other approaches that could be implemented.

In brief, the five approaches presented here include: (1) An administrative approach that would upgrade an existing Agency-maintained facility identification data base, (2) establishment of an EPA-State non-regulatory data management partnership to develop and maintain facility identification data and the necessary linkages between information systems, (3) a distributed information system in which EPA would not establish a central facility identification data base but would rely on building connections to State systems, (4) a regulatory approach that would require consolidated reporting of facility data to EPA or the States while eliminating duplicative reporting, and (5) an approach that would use existing regulatory authority and establish facility identification reporting requirements by developing new OMB Information Collection Requests (ICR).

A. Approach 1: Upgrade FINDS

EPA's Facility Index System (FINDS) is a data base of facility identification data maintained by the Agency. Facility identification data maintained by each program office data base are consolidated in FINDS and an attempt is made to reconcile discrepancies. The major deficiencies with the current FINDS approach are that the reconciliation occurs after data is entered into programmatic data bases; there is no formal mechanism for correcting the programmatic data bases, and the ''data of record'' continues to be the data contained in the program offices' data base which may be inconsistent across the data bases.

Under the ''Upgrade FINDS'' approach, EPA would conduct a comprehensive clean-up, data reconciliation and restructuring of FINDS. The Agency would need to invest significant additional resources into upgrading the quality of the current FINDS data base by eliminating incorrect records and resolving certain existing discrepancies. The current FINDS data base would then be expanded and new methods would be adopted to share this data with the States, program systems, and the public.

Under this approach, it is envisioned that EPA would assign a single identification number to each facility and use that number in all its data bases, thus supporting the goal of data integration and improving public access. This alternative would put no new obligation on the State or the industry to use the new identification number. Therefore, this approach does not affect the burden on industry and it also does not consolidate reporting data. It does maintain or even increase the burden on EPA to continue to reconcile differences in reported facility data and develop and maintain a consistent facility record.

EPA would have the primary responsibility for data reconciliation under this approach. This reconciliation would continue to occur after data are entered into individual program data bases. There would be a continuing need for staff to use their best judgment to resolve discrepancies and populate certain new data fields. However, the Agency could provide facilities with a voluntary opportunity to review and comment on their facility identification record as is currently done for Federal facilities. (For example, EPA's Federal Facilities Enforcement Office uses the Federal Facilities Tracking System (FFTS) to provide a mechanism for facility records review, modification, and correction by a designated Federal agency representative.) Such a voluntary, interactive review process could be accomplished through EPA's Internet Home Page. EPA would like to receive comments and ideas on these and other mechanisms the Agency could use to provide a facility with an opportunity to review and comment on their facility identification data, regardless of the approach adopted to implement the facility identification initiative.

For those who are interested, EPA's current Home Page address is: http://www.epa.gov. This will provide access to the EPA Server. The ENVIROFACTS system contains a listing for current FINDS records. It can be found under the listing for EPA Data Systems and Software.

B. Approach 2: State/Federal Data Management Model

This approach recognizes that both EPA and the States are recipients of environmental reports from facilities. EPA is the initial recipient of some reports such as the Toxics Release Inventory, and pesticide data under FIFRA. However, most facility-based reports generated as a result of Federal environmental laws and regulations initially are received by States who have been delegated the authority by EPA.

Under this approach, EPA and the States would agree to administrative data management procedures for accomplishing the basic goals of the Facility Identification Initiative. These agreements could, for example, be established through a new performance partnership agreement process or in connection with existing programmatic grants.

The focus of this activity would be a State accepting the primary responsibility for reconciling differences in facility records for reports it collects. The State would maintain a consistent ''master record'' for that facility. EPA and the State would agree upon a standard set of data elements for such records, along with such other tools as a standard data dictionary and standards for timing of facility data records transfer and the acceptable level of data quality.

Under this alternative, EPA would establish a national Facility Identification data base. The State and EPA would agree to apply a unique identifier number to each unique

facility. EPA would then obtain the full facility record from the State. Furthermore, States and EPA would agree that any relevant data transmitted to an EPA program data base about such facilities would have to contain the facility identifier number. Otherwise, that data would not be accepted. In this way, both the State and EPA program data bases could contain the necessary linkage capability to make the Facility Identification Initiative function as envisioned.

There may be cases where EPA receives reports directly from a facility and the State does not maintain the same record for that facility. In those cases, EPA would take direct responsibility for reconciling such facility records, establishing the master record, and assigning a facility identifier number. The State would, thereafter, have full access to such records.

It is also possible that a State may want EPA to include records for ''State-only'' facilities and other geographic entities in its Facility Identification data base. For example, this could include records associated with facilities that report environmental data to the State under the authority of State law. For example, a number of States currently use EPA's Aerometric Information Retrieval System (AIRS) data system as their means of maintaining certain air quality data. These States include both Federally covered as well as any additional facility reports in their data uploads to AIRS.

This non-regulatory approach would be transparent to the reporting facility and would result in no new reporting burden being placed on a facility. It would, however, not result in any direct consolidation of facility data reporting elements and the consequent burden reduction across several collections administered by the State. Voluntary mechanisms could be established for a facility to review and comment on their facility record. This would be left up to the State to administer.

This would be a non-mandatory approach and not all States would want or be able to participate. EPA could establish a process to develop a model agreement and test the concept with as many States as may wish to participate. Thereafter, EPA and the States would need to be willing to fund their respective parts of such an initiative separately.

EPA requests comment on the overall feasibility of such an approach. What specific provisions would be a necessary part of such State/EPA agreements? Ultimately, what level of State participation would be required in such a program (other than 100%) in order for EPA to be able to represent this option as a nationally viable facility identification data set? What should EPA do in situations where the State has accepted only partial delegation (e.g., for all programs except water, etc.)?

C. Approach 3: Distributed System Access

The Agency and its State partners are reexamining their respective roles as co-implementers of environmental regulations. Many EPA programs currently delegate to the States much of the implementation of the national programs. Does this lessen the need for EPA to maintain a national facility-specific data set?

Under this approach, States would pursue facility data integration in a manner that best meets their individual needs. This would represent decentralization of the concept of data integration and would support the concept of States developing their own approaches. A significant question needs to be addressed concerning such an approach. How will EPA obtain the data it needs for determining national and cross-boundary trends, and ensuring a national level playing field? This alternative could hamper the Agency's ability to use or provide integrated data on a national basis. EPA would be dependent upon the State systems for what questions could be answered. This approach would, however, provide the States with maximum flexibility to determine how they would manage their data and provide access to it. EPA could maintain a requirement that it and the public have access to these data systems. EPA could then use the data in these distributed systems to do analysis and special projects and reports. However, in this circumstance EPA would not try to maintain a ''master file'' of facilities that would try to track each facility and any changes thereto. Whether the States should be required to do this needs to be considered. Are there alternative ways of achieving the same goal? Is there a need for consistency across States? Should EPA be responsible for providing the public with a national pointer system to any individual facility and its related data points? Or can the public's need for this information be met through distributed State systems, each of which provides the public access to its data or subsets of its data? Should this decision be a national one, across all States and agencies implementing specific environmental reporting requirements, or should the decision on public access be left to each State?

Another alternative to consider might be a requirement that States provide integrated facility data, but not specify how to do it. EPA could set certain minimum levels of service and a standard set of facility data that would tie together program information in various systems. The States would then implement the approach that makes the most sense to them, given other data projects they may already be involved in. No matter how individual States accomplished data integration, each State would have to develop a system of facility identification which would be applicable across program lines. This might result in a master file or lead program system which would assign identifiers which other State offices would pick up. This could be very similar to Approach 1: Upgrade FINDS, except that the State would not be required to establish a master file similar to FINDS and EPA would not establish and maintain a national data base of all the facilities or even all the Federally regulated facilities maintained at the State level. EPA could then use the data in these distributed systems to do analysis and special projects and reports. Access would be provided from the State and perhaps made available to the public and EPA through the Internet or other electronic medium. EPA could rely on the current movement of States to the Internet and World Wide Web where more and more State data are being made accessible electronically. This could obviate the need for a single EPA-managed system to integrate data. Mechanisms for integrating the more important facility elements at a local or regional basis could then be developed. This would allow systems to remain distributed, but would allow EPA or the public to obtain answers to their questions about a regulated entity.

D. Approach 4: Collecting Data by Rule

This approach involves EPA promulgation of a rule that would require certain Federally regulated data submitters to report (or verify) a standard set of facility data. The responsibility for reconciliation of differences in facility data submissions and updating of the facility record would rest with the facility. EPA believes that it could reasonably cite multiple existing statutory authorities as the basis for promulgating a rule to establish and maintain a separate, consistent, facility data record and appropriately streamline the reporting of facility data elements under existing rules to reduce duplication of reporting.

Definitions of what is to be reported in this rule (i.e., the term ''facility''), would be cross-cutting and not

dependent upon the differing regulatory and statutory definitions that apply in any individual rule. The rule would also establish a time frame for the initial report and set forth any requirements for ongoing review and correction of the data record.

A rule process would involve three basic changes:

(1) EPA would place cross references into existing rules advising the regulated ''person'' that they are subject to the new consolidated facility data reporting requirements.

(2) A Facility Identification number would then be added as a required data element in those existing rules allowing the form(s) authorized by those existing rules to include the new, consistent identifier number for that facility.

(3) Existing rules and reporting forms would also be amended to eliminate certain data elements that would also be present in a Facility Identification rule. However, basic name and location address necessary for data validation purposes on any current form would not be eliminated.

It is envisioned that facilities that are subject to one or more Federal environmental reporting requirements that are identified in the rule would be subject to the facility data reporting requirements of a potential rule. The reporting requirements identified in the rule would be site-specific, of a fixed location (e.g., mobile source regulation would be outside the scope); and would have to require periodic reporting, or could be a one-time application and/or registration with periodic follow-up. One-time notifications, surveys, and incident reports would not be considered within the scope of a new rule. Based upon this draft criteria, EPA has identified numerous data collections that it considers to be potentially within the scope of such a facility data reporting rule. These data collections are listed in Table 1 in Unit III.B. of this Notice.

The Facility Identification data reported would be included in a central data base. This data base would be accessible to EPA, States, and the public. This approach could support most of the goals of a Facility Identification Initiative. By establishing a uniform set of place-based data, overlapping data elements could be reduced. Additionally, this reduction could be representative of the first step toward reporting data consolidation. Initially the burden reduction aspect of this approach may not be realized because a new reporting requirement would be established. However, over time the elimination of overlapping data elements from multiple rules could provide a net burden decrease.

The workgroup discussed a number of other issues and options associated with development of a rule. The rule-related issues and options are presented in detail in a document titled ''Support Document for Facility Identification Initiative: Notice and Request for Comment'' which is available as part of the Public Record for this Notice. This document may also be found on the Key Identifiers Project Page of EPA's World Wide Web Home Page. The address is http: //www.epa.gov/Internet/OPPTS or http: //www.epa.gov/EPAHome/Initiatives.html. Included in the Support Document, for comment, are the following:

1. *State and Federal models for flow of data.* A critical determination in implementing a rule will be how the data is collected. The Agency has looked at five rule-based models for collecting the data and entering it into a Facility Identification data base. These include a Federal collection, a State-only collection and, three variations of a State and Federal hybrid collection. EPA is interested in receiving comments on each of these models.

2. *Frequency and timing of facility identification reports.* Related issues discussed in the Support Document include: (a) Setting an initial reporting time-frame; (b) submitter verification of existing Agency facility record to potentially minimize burden on data submitters; (c) options for phasing in the requirement for submitting the initial report; (d) addressing initial submissions by new facilities reporting after promulgation of the rule.

3. *Reviewing and updating the facility identification record.* Keeping a Facility Identification data base current would be a long-term challenge. It is essential that the Facility Identification record reflect the most current information about a facility because it would be the overall reference used by multiple Agency data systems and data users. Therefore, if a new reporting requirement is adopted, the Agency must consider how frequently the Facility Identification data should be reviewed and updated once the facility's record is established through initial reporting. The Agency must balance the need for keeping the data accurate with the burden association with the ongoing nature of such submissions. The following options for ongoing review and updating of the Facility Identification data base are presented for comment in the Support Document: (a) Mandated periodic review and update; (b) updating only when changes occur; (c) report changes as they occur, and verify periodically, and; (d) incorporate in the current submission.

E. ICR-Only Approach

This approach is also a data reporting requirement and would involve many of the same issues as outlined in D. of this Unit. Under this approach, however, EPA would not revise regulations but would prepare a new Information Collection Request (ICR). An ICR outlines burdens and costs associated with information collections, and is required to be prepared by the Agency and approved by the Office of Management and Budget under provisions of the Paperwork Reduction Act.

The new ICR prepared under this approach would seek approval under the provisions of the Paperwork Reduction Act to centrally collect facility identification information that is currently collected under many separate rules. Those rules are currently supported by separate ICRs. In effect, EPA would consolidate facility data reporting into one new form and set of instructions approved by a new ICR. At the same time, all relevant existing forms approved by current ICRs would be modified to eliminate, where possible, existing duplicative facility data elements. The burden calculations of the existing ICRs would also be modified as appropriate to reflect the removal of reporting elements. The existing regulations would not be modified. Instead, the facility identification data requirements in each set of regulations would be fulfilled by submission of the consolidated facility information under the new ICR.

There could be certain advantages to this approach. First, this approach could provide an expedited means of achieving the practical changes necessary to consolidate facility data reporting and streamline the facility data sections of many existing reporting forms. Also, under revised provisions of the Paperwork Reduction Act, the ICR development mechanism provides expanded opportunity for public review and comment. This is not the equivalent of notice and comment rulemaking, but it does offer the public an opportunity to affect the substance of the data collection requirement prior to the Agency's submission of the ICR to OMB.

A potential disadvantage is that the ICR-only approach may not provide the long-term stability necessary for such a comprehensive data management program. Without the backing of a codified requirement, it could be more vulnerable to discontinuation. Such a lack of long-term commitment could be very disruptive and wasteful of the

investments made by all parties involved in both supplying and managing the data.

III. Cross Cutting Issues

EPA believes that there are a number of common questions that must be addressed regardless of the approach chosen to implement the Facility Identification Initiative. In order to create a comprehensive facility record, the question arises of whether we need to develop a comprehensive definition of ''facility''? What environmental data collections (i.e., which facilities) should be included in the Initiative? What should the comprehensive facility record contain? Are there any confidentiality concerns with the development and access to such a comprehensive facility data record? How can we take advantage of evolving technology to meet the information management challenges of the Facility Identification Initiative?

A. Facility Definition

1. *Rationale for a facility definition*. As stated previously, one of the goals of the Facility Identification Initiative would be to establish a streamlined method for identifying a facility across various, separate environmental data collections. No matter how the Facility Identification Initiative is implemented, EPA believes that a standard concept of facility is central to the development of a successful program. For purposes of developing a consolidated ''facility-specific'' record, it is essential that all parties involved have an opportunity to review and comment on the need for, and potential elements of, a ''facility'' term or definition. For purposes of further discussion in this Notice, EPA will use the term ''facility.''

The EPA workgroup considered the issue of how to define the term ''facility'' for purposes of the Facility Identification Initiative. It identified three basic attributes which it believed needed to be considered in constructing a definition.

(1) First is the fixed, spacial or geographic attribute of a facility. Generally speaking, regulated activities occur within a physical boundary, usually a real estate property boundary. In many cases (but not always), there is a ''street address'' that corresponds with this physical location, and other spacial coordinates can be used to identify or define the location.

(2) Next, there is the attribute of ownership or control. Generally speaking a facility is owned or operated by a legal person (i.e. an individual, corporation, or government). Therefore, another parameter for a discrete ''facility'' is that the activities/property/physical boundary is owned or operated by the same person. Take, for example, the situation in which an operation owned by one person is physically surrounded by another persons operation. That separate ownership would be the critical factor in distinguishing one facility from the other.

(3) Finally, there is the attribute of time. That is, the attributes of both physical composition and ownership/control can change with time. Obviously, facility ownership can change and so can the physical boundaries/components. Additions of operations on adjoining properties as well as sale of parts of a location can result in physical changes to a facility and, subsequently, changes to what that facility may have to report under environmental laws and regulations.

2. *Draft facility definition*. EPA believes that developing a facility concept acceptable to all parties involved could ensure both the success and the longevity of the Facility Identification Initiative and data consolidation in general. However, EPA would not intend for a definition of ''facility'' developed under this initiative to alter or affect existing statutory and regulatory definitions of ''facility'' that guide reporting of substantive data within those collections. The point of reference (e.g., facility, site) for reporting substantive data and the substantive reporting requirements of separate collections would not change with a rule or other action defining ''facility'' for purposes of a Facility Identification Initiative.

EPA believes that it would be appropriate to develop a definition of ''facility'' that could apply across a broad array of current environmental data collections and permit requirements. Therefore the definition would have to be broad enough to encompass the whole of the facility's operations but remain within the physical and ownership attributes as discussed above. The workgroup developed the following draft facility definition for comment:

''All buildings, equipment, structures, and other items located on a single site or contiguous or adjacent sites owned or operated by the same person or persons.''

Under this approach, the outermost perimeter of the single geographic area occupied by the entire entity, including all of its parts or divisions, would constitute the ''facility.''

Incorporated into the draft facility definition are elements that EPA considered to be necessary to achieve the goals of the initiative. First, the definition is holistic, or all encompassing. That is, the definition is comprehensive enough to encompass all activities at a particular facility, including all its parts or divisions. Also, the definition relates to a single piece of geography that can encompass contiguous or adjacent sites. This is an important element in achieving consolidated, facility-specific identification data. Finally, the definition specifies that the property must be under a common ownership or control. This element, in combination with the concept of single geographic area, would ensure that all related parts of a facility are captured in an entity's Facility Identification record.

EPA would like to receive comment on whether a term other than ''facility'' should be used to denote the reference point for consolidated facility identification data. If so, what term should be used instead. EPA realizes that other terms may be used such as ''site,'' ''regulated entity,'' ''establishment,'' or ''reporting unit,'' to name a few. EPA requests comment, particularly from States, on their experience with developing and using such terms, along with the problems and successes they have experienced.

3. *Application of the proposed facility definition*. Use of the facility definition proposed here may result in no change in the way that single establishment facilities represent themselves. Likewise, certain complex installations may currently represent themselves in a holistic manner, using a consistent, single name and address for reporting purposes.

However, EPA recognizes that there may be instances where application of a holistic definition of facility could be problematic or confusing. EPA anticipates that such difficulty might arise for at least four specific types of reporting facilities.

(1) Current rules may require reports from ''sub-entities'' of a facility (e.g. two different Divisions within the same larger facility report different names and addresses as separate hazardous waste disposal units).

(2) Facilities reporting as systems or parts of systems (e.g. railroads, pipelines and other systems in which discrete operating units are ''contiguous'' by virtue of a transportation, property or other system connection).

(3) Disjointed operations carried out by the same person within a larger real estate perimeter (e.g., non-contiguous production and warehouse units of the same company within an industrial park could under the draft definition be considered separate facilities).

(4) Adjacent subsidiaries of the same corporation that are separate business entities could be required to all have a common address as one ''facility.'' EPA is providing a detailed discussion of these scenarios in the Support Document for this Notice (See Unit II.D. of this document).

EPA requests comment on these and any other problematic situations associated with implementing and interpreting the draft definition of facility proposed herein.

4. *Accommodating facility changes over time.* Under the Facility Identification Initiative, EPA will want to obtain reliable identification information for a particular facility. Therefore, the Facility Identification system will need to accommodate business transactions that alter facility identification information over time (e.g., changes in property boundaries or facility ownership). The types of accommodations that EPA is considering are discussed in the Support Document, and the Agency requests comment on these situations and any other related issues.

B. Data Collections Included.

1. *Data collections included in facility identification initiative.* In EPA's efforts to identify the most appropriate data collections (i.e., reporting requirements) to be included for coverage under a Facility Identification Initiative, EPA developed and used the following draft criteria:

(i) The reporting requirement and reports submitted should be site-specific. In other words, the ''who'' information in a submission should relate to the physical location of the permitted or regulated activity.

(ii) The facility covered by the data collection would have to be fixed (e.g., mobile source regulations under the CAA would be outside the scope); and

(iii) The data collection would have to require periodic reporting or could be a one-time application and/or registration with periodic follow-up. One-time notifications, surveys, and incident reports would not be considered within the scope of the Initiative.

Based upon this draft criteria, EPA has identified numerous data collections that it considers to be potentially within the scope of the Facility Identification Initiative. EPA began the identification process by reviewing all of EPA's current Information Collection Requests (ICRs). Detailed matrices were developed showing the specific ICRs considered ''within scope.'' The specific elements included: the responsible EPA program office; the statutory authority; the title of the regulation; the ICR and OMB numbers; the CFR citation; the frequency of reporting; whether or not the ICR was considered to be within the scope of the draft criteria; and, the specific facility data elements required to be reported. The completed matrices for these ''within-scope'' ICRs are available for review in the public record for this Notice.

Appropriate offices within the Agency then reviewed the ICRs for which they have responsibility and compared them to the criteria. The results of this review are presented as Table 1 below. Each listed ICR has its basis in a regulatory and/or statutory provision. Therefore, Table 1, represents a list of Federal actions that could be included under a Facility Identification Initiative. The facility identification data submitted pursuant to the list reporting requirements would be subject to consolidation into one facility record under the Initiative. As an aid to the reader, Table 1 is organized by environmental statute and includes the name of the regulation, the regulatory citation, and the EPA ICR number.

Table 1.—Actions That Could Potentially Be Included Under a Facility Identification Initiative

Regulatory Title	40 CFR Citation	ICR Number
Clean Air Act		
Source Compliance and State Action Reporting	51.100	107
Annual, Updates of Emission Data to Aerometric Information Retrieval System (AIRS)	51.321-51.323	916
New Source Performance Standards (NSPS)	Generally, part 60	
National Emissions Standards for Hazardous Air Pollutants (NESHAPS)	Generally, parts 61 & 63	
CAA Title V - Operating Permits Regulations - Information Requirements	70, 502, 503	1587
Federal Operating Permits Program of the Clean Air Act (part 71)	Part 71	1713
Consolidated ICR for the Acid Rain Core Rules - Permits	Part 72	1633
Consolidated ICR for the Acid Rain Core Rules - Nitrogen Oxides Emission Reduction Program	Part 72	1633
Consolidated ICR for the Acid Rain Core Rules - Opt-In-Program	Part 74	1633
Consolidated ICR for the Acid Rain Core Rules - Continuous Emission Monitoring	Part 75	1633
Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act	Part 68	1656
Recordkeeping and Periodic Reporting of the Production and Consumption of Newly Controlled Ozone Depleting Substances	Part 82, Subparts A & E	1432
Comprehensive Environmental Response, Compensation, and Liability Act		
Continuous Release Reporting Regulation Under CERCLA	302.8	1445
Clean Water Act		

Table 1.—Actions That Could Potentially Be Included Under a Facility Identification Initiative—Continued

Regulatory Title	40 CFR Citation	ICR Number
NPDES Permit Application	122.21, 122.26, 122.44, 122.501	226
National Pollutant Discharge Elimination System (NPDES)/Compliance Assessment Information	122.41, 122.47	1427
Combined Sewer Overflow Policy (CSO), 59 FR 18688 (April 19, 1994)		1680.01
Discharge Monitoring Report	122.21, 122.41	229
Pretreatment Program Information Requirements	403	2
Emergency Planning and Community Right-to-Know Act		
Toxic Release Inventory 313 Reporting	372.25, 372.85	1363
Alternate Threshold for Low Annual Reportable Amounts	372.85	1704
Federal Fungicide, Insecticide, and Rodenticide Act		
Application for Registration of Pesticide-Producing Establishments (EPA Form 3540-8); Notification of Registration of Pesticide-Producing Establishments (EPA Form 3540-8A); Pesticide Report for Pesticide-Producing Establishments (EPA Form 3540-16)	167.20, 167.85	160
Resource Conservation and Recovery Act		
Identification, Listing, and Rulemaking Petitions	260.20(b), 260.22, 261.4(d), 261.4(f)	1189
Notification of Regulated Waste Activity	262, 263, 264, 265, 266, 279	261
1993 Hazardous Waste Report	262.41, 264.75, 265.75	976
Hazardous Waste Generator Standards	262.56(a), 265.56(d), (i), (j)	820
General Hazardous Waste Facility Standards	264.56(d)(2), 264.56(i), (j)	1571
RCRA Hazardous Waste Permit Application and Modifications, Part A	270.1, 270.13, 270.72	262
Part B Permit Application, Permit Modifications and Special Permits	270.1, 270.14(b)	1573
Used Oil Management Standards	279.57	1286
Safe Drinking Water Act		
Public Water Supply Program	142	270
Underground Injection Control Program Facility and Well Inventory Information	144	370
Toxic Substances Control Act		
Partial Updating of TSCA Inventory Data Base; Production and Site Reports	710.32	1011
Toxic Substances Control Act (TSCA) Section 8(a) Preliminary Assessment Information Rule (PAIR)	712	586
Polychlorinated Biphenyls (PCBs): Manufacturing, Processing and Distribution in Commerce Exemptions	750.11, 750.31	857
PCB Disposal Permitting Regulation	761.60	1012
PCB Notification and Manifesting of PCB Waste Activities, and Records of PCB Storage and Disposal	761.180, 761.205, 761.211, 761.218	1446

C. Elements of a Consolidated Facility Record

Another cross-cutting issue is the content of the facility identification data record. Assuming that the Facility Identification Initiative is implemented using a central facility data registry approach, the Agency and the States will need to consider what facility data elements are necessary to maintain. The content of this record is particularly important to the discussion of collection of this data by rule. A rule would need to specify what information elements must be reported and updated over time. This has a direct bearing on the burden issue, both from the standpoint of what elements would constitute a new collection and what elements would be removed from the facility section of existing rules and reporting forms. There is, however, an important difference between what may be part of

a reporting requirement and what EPA and States would decide to include as elements in a facility identification data record. For example, under a reporting rule approach, EPA could decide that it is not necessary to collect a certain data element from facilities. It may, however, be a useful and appropriate data element that can be populated from other existing sources. In short, the ultimate data base structure could be more detailed than the elements of a reporting requirement.

Using a non-reporting/ non-regulatory approach would still call for articulation of a facility identification data structure. One distinction, however, is that the data records would all be populated from existing sources. Therefore, the completeness of any given facility identification data record would be a function of the detail of existing facility data used to develop that consolidated facility data record. This could lead to different decisions about total data structure.

Following is a discussion of data elements that the Agency identified and determined were appropriate for eliciting comment.

1. *Facility Identification number.* This is the unique identifier that would be assigned to a facility, after an initial report or as a result of EPA/State data reconciliation efforts. EPA envisions this to be an ''unintelligent'' number. That is, all or most of the components of the number would be randomly assigned and not relate to any particular attribute of the facility. EPA realizes that some States may have already developed such a unique identifier. In such cases, the Agency would not necessarily need to utilize an additional identifier if a means could be developed to incorporate the States number into the structure of the Facility Identification data base. In addition the Agency's current Facility Index System (FINDS) and some States use the ''EPA ID Number'' or ''RCRA ID Number.'' This is a number beginning with a two letter state prefix followed by 9 digits, plus a check digit. This is an identifier that many but not all facilities carry. Also, it may currently apply to individual sub-entity hazardous waste sites that are part of a larger facility. Thus this number may not be appropriate to apply to a facility at large, particularly if there is more than one such sub-entity within the facility. EPA requests comments on how best to consider structuring a unique Facility Identification number and whether the existing EPA Identification Number (RCRA ID Number) could be utilized.

2. *Facility name.* In most cases, this is likely to be a name that already exists in one or more EPA and/or State records. However, even minor variations in a name (e.g., DeBernardo, de Bernardo, D. Bernardo) can raise questions about the true identity of any given facility, especially in situations where records are stored and reported electronically. Other differences may exist as a result of the variation in the current reporting requirements themselves. Such variations also may exist because different individuals at the facility may have completed different reports in slightly different ways (e.g., Conoco is owned by du Pont, but could be reported as Conoco, duPont - Conoco Div., E. I. du Pont de Nemours, etc.)

EPA wishes to receive comment on what type of guidance, if any, to provide regarding the name to be reported. For example, should the facility record contain a commonly used, ''doing-business-as'' name, or should it represent the legal incorporation name? A ''doing-business-as'' name (i.e, duPont - Conoco Div., rather than E. I. du Pont de Nemours) could provide a unique name that most closely represents the current status of facility records. For large corporations, this would not offer a relatively common appellation shared by many other facilities in many different places. As such, it may provide a facility name more understandable to the public. However, the legal incorporation name does appear in existing business and tax records for the facility and may be a more appropriate standard to cite.

The Agency has also considered the inclusion of space for two facility name elements in a data element dictionary so that both a common and a legal incorporation name could be provided. At this point, however, EPA believes that one name representation would be sufficient and that maintaining more than one name record could be counter to the consistency and consolidation goals of this Initiative as well as potentially unnecessarily increasing the reporting burden.

3. *Facility street (physical) address.* This would usually be the postal address corresponding to the physical location of the facility. In some instances, however, it could be a physical description of location if the facility's mailing address does not correspond to its physical location. An example of the latter case would be an entry such as the following, ''2 miles south of the intersections of State Route 2 and Route 5,'' or a conventional street address, ''123 XYZ Blvd.,'' where mail is not accepted at that address. Such an alternate, physical descriptor is required in several current reporting requirements, such as the Toxic Chemical Release Inventory. EPA believes it is reasonable to include such information, particularly in those cases where the facility mailing address is actually a Post Office box number, or is at an entirely different site, such as a corporate office building away from the site. Such information can aid the data user in understanding the general physical location of the facility and is often critical for spatial data analysis.

4. *Facility mailing address.* This element would be supplied in those cases where the mailing address does not correspond with the actual physical location address of the facility. Examples would be Post Office box numbers or a corporate administrative building not located within the facility itself. This element is necessary for basic purposes of communicating with persons responsible for the operations of the facility.

5. *County, parish, or other jurisdictional indicator.* This data element would indicate jurisdictional location as a part of the standard physical address data. EPA's own experience indicates that this basic data element is very valuable in conducting a wide variety of geographic analyses. Consequently, EPA favors including this data element in the Facility Identification data structure. Furthermore, EPA's experience points to a significant desire on the part of the general public to be able to locate environmental data associated with their county. It can also be an important data quality control check for verifying the address information.

6. *Facility contact.* EPA favors including fields for the name of a person to contact (including telephone number, FAX number, and E-mail address if available) for questions that may arise about the content of the Facility Identification record. EPA would not intend for this data element to represent a contact that applies to all other reporting requirements. Each individual data reporting requirement and system (e.g., the RCRA Biennial Reporting System, BRS, or the Permits Compliance System, PCS) could continue to require the name of a contact person for questions concerning the substantive data submitted to such other systems. It may be more problematic to consider including such a data element if a non-reporting option were implemented. It may be difficult for EPA and the State to make a judgment on filling this element from contact person data available in specific media reports.

7. *Facility SIC code.* The Standard Industrial Classification (SIC) code system is a statistical classification system maintained by the Office of

Management and Budget and used throughout government and industry to describe the economic activities undertaken by business entities. It classifies the activities of business and other ''establishments'' using divisional groupings and a specified numbering system. While not a regulatory system itself, the SIC code system has become the predominant means by which many data users obtain a functional classification of the activities of regulated facilities, and is an essential analysis tool in the area of economics. Among other uses, an accurate and current SIC code is critical to successful industry sector analyses. Such analyses are carried out with increasing frequency for purposes of identifying pollution prevention and compliance assistance opportunities.

Most current data collections obtain one or more SIC codes, usually at the 4-digit level. EPA believes that the facility identification data structure should provide for multiple entries to accommodate situations in which a facility engages in different activities or may have more than one establishment engaged in different primary activities. If EPA were to implement a reporting rule, the Agency would like comment on the appropriateness of requiring such codes to be supplied at an 8-digit level in order to support more refined analyses.

8. *Facility Dun and Bradstreet number.* Dun and Bradstreet is a private, business information service that provides to its customers data on companies that have applied for commercial credit. This type of data can be facility-specific. The D&B Number, as it is commonly called, is a valuable piece of information, allowing data users to correlate current business data, such as sales and numbers of employees, to the environmental data being reported by the facility. In particular, EPA and other government agencies use such correlations to develop estimates of the impact of current and future regulatory requirements. The facility-specific D&B number can also be used to obtain information on corporate ownership and subsidiaries through access to the D&B Information System. For Federal facilities which do not have D&B numbers, it has been suggested that GSA Real Property ID number be substituted.

9. *Parent company name and Dun and Bradstreet number.* Parent company data is also important to a wide variety of data users because this information helps them to understand the relationship between the activity taking place at a specific location and the higher level corporate responsibility for that facility. Several current data collections include reporting of parent company information, including the D&B number. This reporting usually refers to the ultimate U.S. parent company. This will provide information concerning the highest level of corporate control within United States jurisdiction. Should this emphasis on ultimate parent be retained or should the data element apply to the facility's most immediate corporate parent? This information could be particularly useful to individual citizens wanting to determine who is immediately responsible for the actions of a particular facility in their community. EPA requests comment on this issue of the most appropriate identification of the facility's parent company.

10. *Permit numbers/system identifiers.* As new EPA programs/data collections were started, there was a need for each to utilize a tracking number to identify the entity that was reporting. However, all of these activities were mandated by Congress independently of each other at different times and seldom utilized the same number. One primary goal of the Facility Identification Initiative is to develop a facility-based data system that acts as a pointer system to more specific environmental data relating to that facility. This data will include, for example, permit data and emissions data reported by the facility to existing EPA or State data systems. It would, therefore, be very important to establish viable links between the Facility Identification data record and facility-based records in relevant Federal and State systems.

Following is an exemplary list of identifier numbers currently used by various EPA and State programs:

(1) TRIFID — The Toxics Release Inventory Facility Identification Number.

(2) NPDES Permit Number — The National Pollutant Discharge Elimination System Permit Number.

(3) RCRA Identification Number — The Resource Conservation and Recovery Act Identification Number. It is also known as the EPA ID Number.

(4) Various air quality permit numbers and facility identifiers — under authority of the Clean Air Act and administered primarily by the States.

(5) ORIS PL Number — The Office of Regulatory Information Systems Plant Number. This is a facility identification number maintained by the Department of Energy's Energy Information Administration and applies to electric power generation utility facilities. It is used as a facility identifier in EPA's National Allowance data base.

(6) UIC Permit Number — The Underground Injection Well Code Permit Number.

(7) FIFRA Establishment Identification Number — The Federal Insecticide, Fungicide, and Rodenticide Act Identification Number.

(8) PWS Identification Number — The Public Water System Identification Number.

(9) The Federal Facility Identification Number — A number assigned by EPA only to Federal facilities.

(10) State Facility Identification Number — A unique identification number that may have been assigned to the facility by the State (or local) delegated agency.

There are two basic sets of issues associated with permit numbers/system identifiers and the facility identification data structure. First, is it necessary for purposes of supporting linkage to include such identifiers in the Facility Identification data set itself? If, for example, a non-reporting alternative is selected, would the State or EPA have to populate each Facility Identification record with other current permit numbers and relevant system identifiers? As an alternative, would it be sufficient for linkage purposes to add a Facility Identification number field to each existing data base record that relates to that same facility?

The second set of issues relates to a reporting requirement approach. In brief, should a Facility Identification reporting rule include a requirement for the facility to report certain permit numbers/system identifiers in order to support the goal of data linkage?

The workgroup considered several alternatives for collecting such data in connection with the Facility Identification record. First, is the option of ongoing reporting/verification of these identifiers. The advantage to this approach is that it provides a consistent mechanism to update changes in the individual identifiers over time. The disadvantage is that it represents a somewhat heavier long-term reporting burden.

The workgroup also considered an option that would require the reporting of such linking elements but ''sunsetting'' the reporting after a period of time sufficient to establish the linkage. This ''sunset'' provision would mean that these reporting elements would automatically disappear from a rule and EPA would eliminate them, where possible, from a form and reporting instructions after the specified period of time. During preliminary discussions with stakeholders, concern was expressed about how the term sunset may be interpreted. It was

therefore recommended that if sunsetting were included that EPA be specific about the length of time to provide for the transition to the Facility Identification system. If a sunset approach is adopted, how long should EPA provide for the transition?

Finally, the workgroup considered a check-box approach in which it would require that the facility indicate that, for example, it has a NPDES permit or a RCRA identification number. This would provide at least a basic pointer to a system in which records relating to the same facility may be located. This approach would be slightly less burdensome than having to fill in the specific identification number. It would, however, provide an imprecise means of establishing or confirming the necessary linkages, and require a substantial expenditure of Federal and State resources.

EPA requests comment on the issue of maintaining current permit numbers and system identifiers as a means of promoting linkage in connection with a Facility Identification record.

11. *Latitude and longitude coordinates*. EPA and the States currently collect latitude/longitude coordinates under several rules and in connection with facility inspections and other activities. Therefore, another issue to consider is whether latitude and longitude coordinates should be made part of the facility identification data record. If so, should these coordinates be drawn from existing data sources or should, for example, a reporting rule mandate facilities to develop and report these coordinates as part of the exercise of building the Facility Identification record? An important aspect of establishing reliable facility identification involves selecting the elements necessary to describe the facility's location. EPA believes that latitude and longitude coordinates are important for two reasons: (1) They support EPA's goal of place-based or community-based environmental management, and (2) they may provide a universal way to link data.

This data element discussion also has a connection with the holistic facility concept. If data is drawn from several existing sources, which set of coordinates should EPA or the State choose to represent the ''facility''? There may be several to choose from that are both general (e.g the TRI submission) and specific, including those that equate to a wastewater discharge pipe or an air emissions stack. Should the coordinates represent a central point of the facility, the front gate, or does it matter as long as the coordinate is located in the facility? A related factor to consider is the variable degree of accuracy of currently available/reported latitude and longitude data. That is why EPA has developed a Locational Data Policy (Ref. 3) that will require EPA programs to include method, accuracy, and description information in association with any latitude and longitude coordinates they develop. Such a policy would improve the value of these data elements, but requires a higher level of effort on the part of the Agency, the State or the facility to develop and maintain.

If EPA and/or the States pursue a non-reporting approach, what standards and agreements related to latitude and longitude data would have to be developed in order to supply viable data for the Facility Identification record?

If a reporting rule approach is taken, should the facility be required to develop and submit these coordinates or should the States or EPA supply the data for these fields? A decision to require such reporting may not support the goals of burden reduction or reporting element consolidation. Reporting of general latitude and longitude data for the holistic facility would not substitute for reporting more specific latitude and longitude data in the underlying collection. Also, the burden associated with developing and submitting this type of information, along with a necessary indication of the method used to collect it and the accuracy of the data, could be significant in relation to all the other data that may be required by a Facility Identification rule. EPA's preliminary estimates indicate that cost of having industry report latitude/longitude data could approximately equal the cost of developing all the other reporting elements currently under consideration.

Therefore, regardless of the means used to implement the Facility Identification Initiative, EPA believes at this point that it may be sufficient to draw on existing sources and use other methodologies to obtain latitude/longitude data for any given facility. From both new and existing sources, EPA believes that it can improve the quality of this geographic data over time by updating that data with latitude/longitude measurements conducted directly by the Agency, the State, or other authoritative sources.

EPA requests comment on the issue of including latitude and longitude coordinates in the Facility Identification data structure and how best to accomplish it.

D. Supporting Electronic Data Transfer Methods

EPA believes that it will be very important to promote the concepts of electronic data transfer methods in connection with implementing the Facility Identification Initiative. The Agency believes that moving aggressively into these data sharing and transfer methods will increase the efficiency and accuracy of Federal and State data management operations. Furthermore, if a reporting rule approach is adopted, several alternatives are available that can support the goal of minimizing burden on both the regulated community and the government. There are a number of emerging technologies that will be easy to use and will be widely available. Examples of the methods currently being investigated are:

1. *Transmission via fax*. FAX systems are almost universally available in industry and government and allow word copy transmissions that can be received and processed in a machine readable format. This can save resources for both the developer as well as the recipient of the data and can improve data accuracy. This method can be used to send the facility's current record for verification or generally provide compliance materials. The facility would call an 800 telephone number to request such materials. The benefit of a FAX system is that it can accommodate material produced by the facility either manually or electronically.

2. *Transmission via Internet/World Wide Web (WWW)*. EPA currently makes the existing Facility Index System (FINDS) data base available on the WWW. In addition, it is investigating the capability of providing updates to the existing information by posting a request for addition/changes/deletion (archiving) of facility records to the regulated community. Security issues are being analyzed with the goal of finding effective ways to ensure the integrity of the information provided via the World Wide Web.

3. *Electronic submission*. For several years, EPA has used and made available to data submitters specific electronic data transmission formats that EPA would intend to make available for use as part of this initiative. Providers of Facility Identification data would be able to use the electronic data transmission format currently used for other data collections.

4. *Other methods*. In addition to the above data submission/transmission methods, EPA would accept paper submissions, but would prefer to receive paper forms by fax, as described in item

1. above. Other magnetic media submission methods used traditionally, such as floppy disk, are being considered. However, floppy disks may not be efficient for the submission of a small set of facility information in the case of a reporting rule (i.e. a large number of facilities reporting a small amount of data to EPA or the State).

Also, under consideration is submission via commercial online services and electronic mail.

EPA would be interested in receiving comments from States and potential data submitters regarding the most technically feasible and cost effective methods of electronic data transmission for them.

E. Confidential Business Information and Trade Secrets

The type of information under consideration in the Facility Identification Initiative is very general in nature. As currently envisioned, this information would be maintained and/or submitted separately from the substantive data reported under existing rules. Only publicly-accessible data would be included. Given the general nature of the facility identification information and its submission independent of other substantive data, the Agency believes that it is unlikely that facility identification information would qualify for protection as either confidential business information (CBI) or a trade secret.

Although the information being contemplated would not give rise to a CBI claim, and the rule would preclude claims for facility identifier information standing alone, all existing statutory and regulatory protection for CBI and trade secrets would remain intact, should there be a Facility Identification rule. Claims applicable to the link between facility identifier information and other reported information would continue to be asserted and maintained in accordance with the statutory and regulatory provisions applicable to the underlying data collections. Information would continue to be protected in the underlying collections, as appropriate.

EPA takes seriously the obligation to protect CBI and will ensure the continued protection of CBI regardless of the method of developing Facility Identification records. EPA is mindful that safeguards are necessary to ensure that CBI submitted under current rules is not inadvertently made available through a facility identification data profile.

EPA is interested in receiving comments on any CBI-related issues that should be considered under the Facility Identification Initiative.

IV. Questions To Consider

This Unit summarizes a number of questions that the reader should consider when developing comments on this Notice.

(1) Is integrated facility data useful and necessary? Should EPA maintain a national data base of all (or some segment of) regulated facilities in order to fulfill its mission and to allow the public and others access to this information?

(2) What are the specific uses of integrated facility identification data?

(3) Who are the customers for such data and how can they use this data to improve environmental protection?

(4) Is there a benefit to having a national set of data or would access to state collections suffice?

(5) Would a national standard for facility identification, including a commonly applied definition of ''facility'', be a useful first step to integrating facility data across media programs?

(6) How should ''facility'' be defined for purposes of such data consolidation?

(7) Is there a better or more comprehensive term to use for the purposes of facility-specific data collection than ''facility.''

(8) From which existing Federal environmental reporting requirements should facility data be consolidated? Should priorities be set regarding which Federally regulated facilities to cover?

(9) Should the Initiative be limited to facilities reporting under Federal authority only or should a Facility Identification data base include other facilities (e.g. those that only report to a State)?

(10) What data elements would form the optimum consolidated facility identification record?

(11) What methods of electronic data transmission/submission should EPA develop and support?

(12) Are there any CBI issues associated with developing and maintaining a Facility Identification data base?

(13) This Notice outlines a number of possible alternatives for implementing the Facility Identification Initiative. What other approaches should be considered? How would such approaches support the goals of a Facility Identification Initiative?

(14) If a reporting requirement were developed, who should collect the data and who should maintain it — EPA, the States, both?

(15) What reporting provisions or techniques of reporting would minimize the costs of reporting and maintain current data?

(16) Are there non-national alternatives to providing integrated data to the public? In other words, does facility-specific environmental protection require the collection and maintenance of a national data base? Are there needs for national data analyses (in addition to facility-specific analyses) that would warrant such a national data base?

(17) Presuming a system of national data integration is advisable, how best can EPA work with the States to develop such a system?

(18) EPA realizes that there will be impacts to States because of the Facility Identification Initiative. What are potential problems and burdens that States may face under each of the various alternatives to implementing the Facility Identification Initiative?

(19) EPA is aware that a number of States are in the process of implementing programs much like the Facility Identification Initiative. What specific programs have States implemented and what progress has been achieved?

V. Request for Public Comment

EPA requests public comment on all the issues outlined in this Notice regarding the consolidated reporting of facility identification information. Comments should be submitted to the address listed under the ADDRESSES unit. All comments must be received by EPA on or before December 23, 1996.

VI. Public Participation

This Notice reflects input received early in the process from various environmental and industrial interest groups, and States. For example, EPA held ''stakeholders'' meetings on the project on June 23, 1995, in which the project's concepts to date were outlined and oral comments were received. Copies of materials made available at that meeting and a summary of comments is available in the public record for this Notice.

In addition, the Agency entered into a cooperative agreement with the National Governors' Association (NGA). The purpose of the cooperative agreement was to provide a forum for States to exchange information about their respective uniform reporting efforts, to learn about the Agency's Facility Identification Initiative, and to share their experiences with EPA. The forum, consisting of 12 State representatives selected by NGA officials, has held a number of meetings to discuss the Facility Identification Initiative concepts. The individual meeting summaries will also be made part of the public record for this Notice.

EPA intends to hold one or more public meetings in connection with this Notice. Separate notice of such meeting or meetings will be published in the Federal Register.

VII. Public Record

A record has been established for this Notice under docket number OPPTS-00186 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI or trade secret, is available for inspection from noon to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in the TSCA Nonconfidential Information Center, Rm. NE-B607, 401 M St., SW., Washington, DC 20460.

Electronic comments can be sent directly to EPA at:

oppt.ncic@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of any special characters and any form of encryption. The official record for this Notice, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official record for this Notice which will also include all comments submitted directly in writing. The official public record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

VIII. References

(1) ''Using Information Strategically to Protect Human Health and the Environment: Recommendations for Comprehensive Information Resources Management'' issued by the Information Resources Management Strategic Planning Task Force, a subcommittee of the National Advisory Council for Environmental Policy and Technology (NACEPT), August 1994, EPA 270-K-94-002.

(2) EPA 2100 Information Resources Management Policy Manual, Chapter 13 - Locational Data, April 8, 1991.

List of Subjects

Environmental protection.

Dated: September 26, 1996.

Carol M. Browner,

Administrator.

[FR Doc. 96–25378 Filed 10–4–96; 8:45 am]

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federal register

Monday
October 7, 1996

Part VII

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 808, 812, and 820 Medical Devices; Current Good Manufacturing Practice (CGMP); Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 808, 812, and 820

[Docket No. 90N–0172]

RIN 0910–AA09

Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising the current good manufacturing practice (CGMP) requirements for medical devices and incorporating them into a quality system regulation. The quality system regulation includes requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of medical devices intended for human use. This action is necessary to add preproduction design controls and to achieve consistency with quality system requirements worldwide. This regulation sets forth the framework for device manufacturers to follow and gives them greater flexibility in achieving quality requirements.

DATES: The regulation is effective June 1, 1997. For more information on compliance with 21 CFR 820.30 see section IV. of this document.

Written comments on the information collection requirements should be submitted by December 6, 1996.

ADDRESSES: Submit written comments on the information collection requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kimberly A. Trautman, Center for Devices and Radiological Health (HFZ-341), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4648.

SUPPLEMENTARY INFORMATION:

I. Background

Manufacturers establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products (food, drugs, biologics, and devices) are known as CGMP's. CGMP requirements for devices in part 820 (21 CFR part 820) were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(f)), which was among the authorities added to the act by the Medical Device Amendments of 1976 (Pub. L. 94–295).

Under section 520(f) of the act, FDA issued a final rule in the Federal Register of July 21, 1978 (43 FR 31 508), prescribing CGMP requirements for the methods used in, and the facilities and controls used for the manufacture, packing, storage, and installation of medical devices. This regulation became effective on December 18, 1978, and is codified under part 820. Except for editorial changes to update organizational references in the regulation and revisions to the list of critical devices that was included in the preamble to the final regulation, the device CGMP requirements have not been revised since 1978. This final rule is the result of an extensive effort begun in 1990 to revise this regulation.

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629), enacted on November 28, 1990, amended section 520(f) of the act, providing FDA with the authority to add preproduction design controls to the CGMP regulation. This change in law was based on findings that a significant proportion of device recalls were attributed to faulty design of product. Specifically, in January 1990, FDA published the results of an evaluation of device recalls that occurred from October 1983 through September 1989, in a report entitled ''Device Recalls: A Study of Quality Problems'' (Ref. 1). (See 55 FR 21108, May 22, 1990, where FDA announced the availability of the report.) FDA found that approximately 44 percent of the quality problems that led to voluntary recall actions during this 6-year period were attributed to errors or deficiencies that were designed into particular devices and may have been prevented by adequate design controls. These design-related defects involved both noncritical devices (e.g., patient chair lifts, in vitro diagnostics, and administration sets) and critical devices (e.g., pacemakers and ventilators). Also in 1990, the Department of Health and Human Services' Inspector General conducted a study entitled ''FDA Medical Device Regulation From Premarket Review to Recall'' (Ref. 2), which reached similar conclusions. With respect to software used to operate medical devices, the data were even more striking. A subsequent study of software-related recalls for the period of fiscal year (FY) 1983 through FY 1991 indicated that over 90 percent of all software-related device failures were due to design-related errors, generally, the failure to validate software prior to routine production (Ref. 3).

The SMDA also added new section 803 to the act (21 U.S.C. 383) which, among other things, encourages FDA to work with foreign countries toward mutual recognition of CGMP requirements. FDA undertook the revision of the CGMP regulation to add the design controls authorized by the SMDA to the CGMP regulation, as well as because the agency believed that it would be beneficial to the public and the medical device industry for the CGMP regulation to be consistent, to the extent possible, with the requirements for quality systems contained in applicable international standards, primarily, the International Organization for Standards (ISO) 9001:1994 ''Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing'' (Ref. 4), and the ISO committee draft (CD) revision of ISO/CD 13485 ''Quality Systems—Medical Devices—Supplementary Requirements to ISO 9001'' (Ref. 5).

This action is being taken under those provisions of the SMDA and in response to the following: (1) Notices that appeared in the Federal Register of April 25, 1990 (55 FR 17502), and in the Federal Register of April 17, 1991 (56 FR 15626), that announced meetings of the agency's Device Good Manufacturing Practice Advisory Committee (GMP Advisory Committee), at which the need for revisions to the CGMP regulation was explored; (2) an advance notice of proposed rulemaking (ANPRM) that appeared in the Federal Register of June 15, 1990 (55 FR 24544), that announced the agency's intent to revise the CGMP regulation; (3) a notice of availability of a document that appeared in the Federal Register of November 30, 1990 (55 FR 49644), entitled ''Medical Devices; Current Good Manufacturing Practices (CGMP) Regulations Document; Suggested Changes; Availability'' (Ref. 6) and comments solicited from the public about the document; (4) a proposed rule in the Federal Register of November 23, 1993 (58 FR 61952), (Ref. 7) and comments solicited from the public about the proposal; (5) a notice of availability that appeared in the Federal Register of July 24, 1995 (60 FR 37856), announcing the availability of the ''Working Draft of the Current Good Manufacturing Practice (CGMP) Final Rule'' (hereinafter referred to as the Working Draft) (Ref. 8) and comments

solicited from the public about the Working Draft; (6) testimony at an August 23, 1995, open public meeting announced in the Federal Register (60 FR 37856); (7) and testimony and advisory committee recommendations from the September 13 and 14, 1995, meeting of the GMP Advisory Committee announced in the Federal Register of August 24, 1995 (60 FR 44036). Thus, FDA's decision to revise the CGMP regulation is based on changes in the law made by the SMDA, the agency's discussions with others including its GMP Advisory Committee, responses to the Federal Register notices on this matter, FDA's analysis of recall data, its experience with the regulatory application of the original CGMP regulation, and its assessment of international quality standards.

The agency's final rule embraces the same ''umbrella'' approach to the CGMP regulation that is the underpinning of the original CGMP regulation. Because this regulation must apply to so many different types of devices, the regulation does not prescribe in detail how a manufacturer must produce a specific device. Rather, the regulation provides the framework that all manufacturers must follow by requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device. FDA has made changes to the proposed regulation and the Working Draft, as the final rule evidences, to provide manufacturers with even greater flexibility in achieving the quality requirements.

The Supreme Court recently addressed the preemptive effect, under section 521 of the act (21 U.S.C. 360k), of the original CGMP regulation and other FDA requirements for medical devices on State tort actions. In *Medtronic, Inc.* v. *Lohr,* 116 S. Ct. 2240 (1996), the Supreme Court gave substantial deference to the agency's interpretation of section 521 of the act found at § 808.1 (21 CFR 808.1). The Court noted that CGMP requirements are general rather than ''specific requirements applicable to a particular device,'' and that State common law remedies are similarly general, and do not establish a ''substantive requirement for a specific device.'' (*Lohr* at 2257; see also § 808.1(d) and (d)(6)(ii).) Moreover, the Court drew a distinction between remedies and requirements, noting that while common law tort actions may provide remedies different from those available under the act, no preemption occurs unless the substantive requirements of the State law are ''different from, or in addition to,'' those imposed by the act. (See *Lohr* at 2255.) Under the Supreme Court's analysis in *Lohr,* the requirements imposed by the original CGMP regulation would rarely have preemptive effect.

FDA believes that the reasoning of *Medtronic* v. *Lohr* applies equally to the new quality system regulation, which, as does the original CGMP regulation, prescribes requirements that apply to medical devices in general, rather than to any particular medical device. Therefore, FDA has concurrently amended part 808 (21 CFR part 808) to make clear the new quality system regulation does not preempt State tort and common law remedies.

II. Decision to Make a Working Draft Available for Comment

In the Federal Register of November 23, 1993, the agency issued the proposed revisions to the CGMP regulation, entitled ''Medical Devices; Current Good Manufacturing Practice (CGMP) Regulations; Proposed Revisions; Request for Comments,'' and public comment was solicited. After the proposal issued, FDA met with the Global Harmonization Task Force (the GHTF) Study Group in early March 1994, in Brussels, to compare the provisions of the proposal with the provisions of ISO 9001:1994 and European National Standard (EN) 46001 ''Quality Systems—Medical Devices—Particular Requirements for the Application of EN 29001'' (Ref. 9). ISO 9001:1994 and EN 46001:1994 are written as voluntary standards, but when used to fulfill the requirements of the European Medical Device Directives, or other national regulations, these standards are mandatory requirements similar to the CGMP requirements. The GHTF includes: Representatives of the Canadian Ministry of Health and Welfare, the Japanese Ministry of Health and Welfare, FDA, and industry members from the European Union (EU), Australia, Canada, Japan, and the United States. The participants at the GHTF meeting favorably regarded FDA's effort toward harmonization with international standards. The GHTF submitted comments, however, noting where FDA could more closely harmonize to achieve consistency with quality system requirements worldwide. Since the proposal published, FDA has also attended numerous industry and professional association seminars and workshops, including ISO Technical Committee (TC) 210 ''Quality Management and Corresponding General Aspects for Medical Devices'' meetings, where the proposed revisions were discussed.

The original period for comment on the proposal closed on February 22, 1994, and was extended until April 4, 1994. Because of the heavy volume of comments and the desire to increase public participation in the development of the quality system regulation, FDA decided to publish the notice of availability in the Federal Register to allow comment on the Working Draft before issuing a final regulation.

The Working Draft represented the agency's views at the time on how it would respond to the many comments received, and on how the agency believed a final rule should be framed. FDA solicited public comment on the Working Draft until October 23, 1995, to determine if the agency had adequately addressed the many comments received and whether the agency had framed a final rule that achieved the public health goals to be gained from implementation of quality systems in the most efficient manner.

III. Open Public Meeting and GMP Advisory Committee Meeting

FDA held an open public meeting on the quality system regulation on August 23, 1995. The public meeting consisted of prepared presentations followed by an open discussion period. Both the agency and the participants found the meeting to be very productive in focusing attention on the few main areas of concern in the Working Draft. The main issues were: The application of the regulation to component manufacturers; the application of the regulation to third party servicers and refurbishers; and the implementation timeframe of the final rule. A transcript of the proceedings of the public meeting, as well as data and information submitted to FDA during the public meeting, are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

There also was a meeting of the GMP Advisory Committee on the Working Draft on September 13 and 14, 1995. A notice of the meeting was published in the Federal Register of August 24, 1995. FDA made a brief presentation to the committee on the changes from the 1993 proposal to the 1995 Working Draft and discussed some changes that FDA was recommending as a result of the August 1995 meeting. Two consultants also made presentations to the committee, one a representative from ISO TC 176 (the TC that authored the ISO 9000 series) and the other a representative from the European Committee for Standardization (CEN). The remainder of the meeting consisted of prepared

presentations from the public and the committee's discussion on the main issues.

The overwhelming majority of the committee members believed that the Working Draft met the public health needs, gave manufacturers sufficient flexibility to comply with the regulation, and met the agency's goal of harmonizing the quality system requirements with those of other countries. The GMP Advisory Committee strongly supported FDA's recommendation, in response to the August 1995 public meeting, to not include component manufacturers under this final rule. However, the GMP Advisory Committee was clearly divided on several issues related to the proposed regulation of third party servicers and refurbishers. A transcript of the proceedings of the GMP Advisory Committee meeting, as well as data and information submitted to FDA during the meeting, are available from the Dockets Management Branch (address above).

After considering the written comments and the views expressed at meetings with the GHTF, at the August 1995 public meeting, and at the September 1995 GMP Advisory Committee meeting, FDA is publishing this final rule. A summary of changes from the July 1995 Working Draft to the final rule is contained at the end of this preamble.

IV. Implementation of the Final Rule

FDA has decided, in response to the many comments and concerns expressed about the need for more time to implement design controls, to implement the final rule in two stages. Under stage one, on June 1, 1997, approximately 1 year after this rule is published in the Federal Register, all elements of the final rule become effective. However, with respect to the design control requirements in § 820.30, as long as manufacturers are taking reasonable steps to come into compliance, FDA will implement a special 1-year transition program, with a midcourse review, during which official agency action will not be initiated, including FDA Form 483 observations, warning letters, or enforcement cases, based on failure to comply with § 820.30. Under stage two, beginning June 1, 1998, FDA will treat noncompliance with design control requirements in § 820.30 the same as noncompliance with other provisions of the CGMP regulation.

To prepare for stage one of this implementation plan, FDA intends to develop, by April of 1997, a strategy for inspecting the design control requirements. Both industry and FDA field investigators will then be trained on this inspectional strategy for design controls during April and May 1997. Starting June 1, 1997, manufacturers will be inspected for compliance with all the new quality system requirements, including design controls, in the manner described in the inspectional strategy. However, as part of the transition program, from June 1, 1997, for a period of 1 year, although FDA will inspect firms for compliance with the design control requirements, the field will issue any observations to the manufacturer on a separate design control inspectional strategy report, not on FDA Form 483. The design control inspectional strategy report will be made a part of the manufacturer's establishment inspection report (EIR), but the observations relating to § 820.30 will not be included in any warning letters or regulatory actions during this initial 1-year period. FDA notes that it can, at any time, take action against unsafe or adulterated medical devices under different regulatory or statutory authorities. FDA wants to emphasize that *manufacturers are required to take reasonable steps to come into compliance with the design control requirements during the June 1, 1997, to June 1, 1998, period.*

FDA also emphasizes that this transition period relates only to the design control requirements of § 820.30, and that beginning June 1, 1997, the agency will issue observations on FDA Form 483's, issue warning letters, and take any necessary regulatory action for violations of all other provisions of the CGMP final rule. The time period from June 1, 1997, to June 1, 1998, is intended to allow both the industry and FDA field investigators time to become familiar with the design control requirements and the enforcement aspects of this new area.

Finally, as described elsewhere in this preamble, FDA intends to conduct a midcourse review of the new design control requirements during the transition year (June 1997 to June 1998). Specifically, the results of the first several months of design control inspections will be reviewed by early 1998. FDA will review all of the completed design control inspectional strategy reports that were given to manufacturers from between June 1, 1997, through December 1, 1997. The completed strategy reports will be reviewed with particular attention paid to clarity of information obtained, the appropriateness of the information collected with respect to the design control requirements, the appropriateness of the questions on the inspectional strategy, the manner in which the investigators are writing out their observations, and any requirements that seem to be giving manufacturers a problem or where there might be misunderstandings as to what the regulation requires. FDA will then hold an open public meeting in early 1998 to discuss with industry these findings and to further explore any concerns industry might be having in implementing the new design control requirements. As a result of the midcourse review and open public meeting, FDA might hold additional workshops, meetings, and/or training sessions.

Any midcourse adjustments to the inspectional strategy will be instituted and made public by the spring of 1998. Also during this midcourse review, FDA will evaluate the information gathered at that point and determine if the design control requirements as written in this final rule are appropriate to obtain the goals expressed in this preamble. FDA will consider minor or even major changes, based on experience to date. Any necessary adjustments or proposed revisions will be published in the Federal Register and comments will be solicited as necessary during the spring of 1998. This implementation strategy is responsive to requests by industry for FDA to harmonize the quality system regulation's implementation with the mandatory date for implementation of the EU's Medical Device Directive, which is June 1998. However, if during the midcourse review of stage one it is determined that the industry and/or FDA needs more time to fully implement the design control requirements, FDA will publish an extension of the regulatory implementation date for design control requirements prior to June 1, 1998.

V. Response to Comments and Rationale for Changes

Approximately 280 separate individuals or groups commented on the proposal published in the Federal Register of November 23, 1993, and approximately 175 separate individuals or groups commented on the Working Draft that was announced in a notice of availability published in the Federal Register on July 24, 1995. FDA made many changes in response to the comments. Most of the changes were made in response to specific comments, in response to comments for clarity, understanding, and readability, or to further harmonize FDA requirements with international standards, as many comments requested.

Numerous comments stated that industry was very pleased with FDA's

Working Draft and the effort that was made to harmonize with ISO, as well as to engage industry in commenting on the Working Draft through the open public meeting and the GMP Advisory Committee meeting that were held in August and September 1995, respectively.

FDA's responses to the comments received on the proposal and the Working Draft, as well as explanations for the changes made, follow.

A. General Provisions (Subpart A)

i. Scope (§ 820.1)

1. The title of the regulation, as reflected in this section, has been changed from the ''Current Good Manufacturing Practices (CGMP)'' regulation to the ''Quality System'' regulation. This revision follows the suggestion underlying many comments on specific provisions that FDA generally harmonize the CGMP requirements and terminology with international standards. ISO 9001:1994, ISO/CD 13485, and EN 46001 employ this terminology to describe the CGMP requirements. In addition, this title accurately describes the sum of the requirements, which now include the CGMP requirements for design, purchasing, and servicing controls. CGMP requirements now cover a full quality system.

FDA notes that the principles embodied in this quality system regulation have been accepted worldwide as a means of ensuring that acceptable products are produced. While the regulation has been harmonized with the medical device requirements in Europe, Australia, and Japan, as well as the requirements proposed by Canada, it is anticipated that other countries will adopt similar requirements in the near future.

FDA, however, did not adopt ISO 9001:1994 verbatim for two reasons. First, there were complications in dealing with the issue of copyrights and, second, FDA along with health agencies of other governments does not believe that for medical devices ISO 9001:1994 alone is sufficient to adequately protect the public health. Therefore, FDA has worked closely with the GHTF and TC 210 to develop a regulation which is consistent with both ISO 9001:1994 and ISO/CD 13485. FDA made several suggestions to TC 210 on the drafts of the ISO/CD 13485 document in order to minimize differences and move closer to harmonization. In some cases, FDA has explicitly stated requirements that many experts believe are inherent in ISO 9001:1994. Through the many years of experience enforcing and evaluating compliance with the original CGMP regulation, FDA has found that it is necessary to clearly spell out its expectations. This difference in approach does not represent any fundamentally different requirements that would hinder global harmonization. In fact, numerous comments expressed their approval and satisfaction with FDA's effort to harmonize the quality system requirements with those of ISO 9001:1994 and ISO/CD 13485.

2. One comment suggested that the term ''purchasing'' in the scope be deleted because it could be interpreted to mean the purchase of finished medical devices by health care institutions and medical professionals, instead of the purchase of components and manufacturing materials as intended.

FDA agrees and has deleted the term ''purchasing'' throughout the regulation when used in this context.

3. Several comments suggested that § 820.1(a)(1) should not state that the regulation establishes the ''minimum'' requirements because it implies that compliance with the stated requirements may be insufficient. They asked that FDA delete the word ''minimum,'' to avoid having auditors search for additional requirements.

FDA does not believe that the provision would have required that manufacturers meet additional requirements not mandated by the regulation but has modified the section to clarify its intent by stating that the regulation establishes the ''basic'' requirements for manufacturing devices. The quality system regulation provides a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements. The regulation provides the flexibility necessary to allow manufacturers to adopt advances in technology, as well as new manufacturing and quality system procedures, as they become available.

During inspections, FDA will assess whether a manufacturer has established procedures and followed requirements that are appropriate to a given device under the current state-of-the-art manufacturing for that specific device. FDA investigators receive extensive training to ensure uniform interpretation and application of the regulation to the medical device industry. Thus, the agency does not believe that FDA investigators will cite deviations from requirements not contained in this part. However, as noted above, FDA has altered the language of the scope to make clear that additional, unstated requirements do not exist.

4. A few comments suggested eliminating the distinction between critical and noncritical devices, thus eliminating the need for distinct requirements for critical devices. Other comments disagreed, asserting that eliminating the distinction would increase the cost of production of low-risk devices without improving their safety and effectiveness.

FDA agrees in part with the comments that suggest eliminating the distinction between critical and noncritical devices and has eliminated the term ''critical device'' from the scope, definitions, and regulation in §§ 820.65 *Critical devices, traceability* and 820.165 *Critical devices, labeling.* However, FDA has retained the concept of distinguishing between devices for the traceability requirements in § 820.65. As addressed in the discussion under that section, FDA believes that it is imperative that manufacturers be able to trace, by control number, any device, or where appropriate component of a device, that is intended for surgical implant into the body or to support or sustain life whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user.

The deletion of the terminology will bring the regulation in closer harmony with ISO 9001:1994 and the quality system standards or requirements of other countries.

Finally, FDA notes that eliminating the term ''critical device'' and the list of critical devices does not result in the imposition of new requirements. In fact the new regulation is less prescriptive and gives the manufacturer the flexibility to determine the controls that are necessary commensurate with risk. The burden is on the manufacturer, however, to describe the types and degree of controls and how those controls were decided upon. Such determinations are made in accordance with standard operating procedures (SOP's) established by the manufacturer.

5. In response to numerous comments, FDA has added the sentence ''If a person engages in only some operations subject to the requirements in this part, and not in others, that person need only comply with those requirements applicable to the operations in which he or she is engaged.'' This sentence was added to clarify the scope of the regulation and

the responsibility of those who fall under this regulation. The wording is the same as that used in the drug CGMP.

6. Several comments recommended that the short list of class I devices subject to design control requirements be deleted from the regulation and be placed in the preamble, to allow additions or deletions without requiring a change to the entire regulation. Others commented that the list of class I devices should be entirely eliminated to harmonize with Europe and Japan.

FDA disagrees that the list of devices subject to design control requirements should be deleted from the regulation. FDA has experienced problems or has concerns with the class I devices listed and has determined that design controls are needed for the listed devices. Further, placing the list in the regulation establishes the requirements related to those devices, and is convenient for use by persons who are not familiar with, or who do not have access to, the preamble. Further, FDA notes that individual sections of a regulation may be revised independent of the remainder of the regulation.

7. Numerous written comments and persons who testified at the August and September 1995 meetings stated that application of the regulation to component manufacturers would increase product cost, with questionable value added to device safety and effectiveness, and that many component suppliers would refuse to supply components or services to the medical device industry. This would be especially likely to occur, it was suggested, where medical device manufacturers account for a small fraction of the supplier's sales.

FDA believes that because of the complexity of many components used in medical devices, their adequacy cannot always be assured through inspection and testing at the finished device manufacturer. This is especially true of software and software-related components, such as microprocessors and microcircuits. Quality must be designed and built into components through the application of proper quality systems.

However, FDA notes that the quality system regulation now explicitly requires that the finished device manufacturer assess the capability of suppliers, contractors, and consultants to provide quality products pursuant to § 820.50 *Purchasing controls.* These requirements supplement the acceptance requirements under § 820.80. Manufacturers must comply with both sections for any incoming component or subassembly or service, regardless of the finished device manufacturer's financial or business affiliation with the person providing such products or services. FDA believes that these purchasing controls are sufficient to provide the needed assurance that suppliers, contractors, and consultants have adequate controls to produce acceptable components.

Therefore, balancing the many concerns of the medical device industry and the agency's public health and safety concerns, FDA has decided to remove the provision making the CGMP regulation applicable to component manufacturers and return to the language in the original CGMP regulation. This approach was unanimously endorsed by the members of the GMP Advisory Committee at the September 1995 meeting. FDA will continue to focus its inspections on finished device manufacturers and expects that such manufacturers will properly ensure that the components they purchase are safe and effective. Finished device manufacturers who fail to comply with §§ 820.50 and 820.80 will be subject to enforcement action. FDA notes that the legal authority exists to cover component manufacturers under the CGMP regulation should the need arise.

8. One comment stated that proposed § 820.1(a)(2) should be revised to include the District of Columbia and the Commonwealth of Puerto Rico, as in the original CGMP regulation.

FDA agrees with the comment. These localities were inadvertently omitted and have been added to the regulation.

9. FDA added § 820.1(a)(3) on how to interpret the phrase ''where appropriate'' in the regulation, as recommended by the GMP Advisory Committee. This section is consistent with the statement in ISO/CD 13485.

10. Some comments on proposed § 820.1(c) recommended that the section be deleted as it already appears in the act. Others stated that the provision implies that FDA will subject devices or persons to legal action, regardless of the level of noncompliance. Still others suggested that only intentional violations of the regulation should give rise to regulatory action.

FDA disagrees with these comments. The consequences of the failure to comply, and the legal authority under which regulatory action may be taken, are included in the regulation so that the public may be fully apprised of the possible consequences of noncompliance and understand the importance of compliance. FDA notes that the agency exercises discretion when deciding whether to pursue a regulatory action and does not take enforcement action for every violation it encounters. Further, FDA generally provides manufacturers with warning prior to initiating regulatory action and encourages voluntary compliance. The agency also notes, however, that violations of this regulation need not be intentional to place the public at serious risk or for FDA to take regulatory action for such violations.

In response to the concerns regarding the tone of the section, however, the title has been changed. FDA has also deleted the specific provisions referenced in the proposed section with which the failure to comply would render the devices adulterated. The term ''part'' includes all of the regulation's requirements.

11. A few comments on proposed § 820.1(c)(2), now § 820.1(d), requested that the agency clarify what is meant by requiring that foreign manufacturers ''schedule'' an inspection. A few comments stated that FDA was adding new requirements for foreign manufacturers in this section. Others stated that the proposed language would prohibit global harmonization because it would limit third party audits in place of FDA inspections.

FDA has moved the provision related to foreign manufacturers into a separate section and has modified the language. The language in the regulation reflects the language in section 801(a) of the act (21 U.S.C. 381(a)). FDA disagrees that it is adding new requirements for foreign manufacturers in § 820.1(d) because the section recites the current requirement and standard used, and is consistent with current agency policy. The agency believes that it is imperative that foreign facilities be inspected for compliance with this regulation and that they be held to the same high standards to which U.S. manufacturers are held. Otherwise, the U.S. public will not be sufficiently protected from potentially dangerous devices, and the U.S. medical device industry will be at a competitive disadvantage.

FDA intends to continue scheduling inspections of foreign manufacturers in advance to assure their availability and avoid conflicts with holidays and shut down periods. However, the language pertaining to the ''scheduling'' of such inspections has been deleted to allow flexibility in scheduling methods.

FDA disagrees that, as written, the language would prohibit inspections by third parties. FDA may use third party inspections, as it uses other compliance information, in setting its priorities and utilizing its resources related to foreign inspections. In this regard, FDA looks forward to entering into agreements with foreign countries related to CGMP

inspections that would provide FDA with reliable inspectional information.

12. Two comments stated that the section on ''Exemptions or variances,'' now § 820.1(e), should require that FDA provide a decision on petitions within 60 days of receipt and state that the agency will take no enforcement action with respect to the subject of the petition until a decision is rendered. The comments said that the petition process is long, arduous, and not practical.

FDA disagrees with the comments. Currently, FDA is required by section 520(f)(2)(B) of the act to respond within 60 days of receipt of the petition, unless the petition is referred to an advisory committee. When the 1978 CGMP regulation was published, there was a prediction that FDA would be overwhelmed with petitions for exemption and variance from the regulation. Over the past 18 years, since the CGMP regulation first became effective, FDA has only received approximately 75 petitions. It is FDA's opinion that few petitions have been received because of the flexible nature of the CGMP regulation. FDA has attempted to write the current regulation with at least the same degree of flexibility, if not more, to allow manufacturers to design a quality system that is appropriate for their devices and operations and that is not overly burdensome.

Guidelines for the submission of petitions for exemption or variance are available from the Division of Small Manufacturers Assistance (the DSMA). The petition guidelines state that FDA will not process a petition for exemption or variance while an FDA inspection of a manufacturer is ongoing. Until FDA has approved a petition for an exemption or variance, a manufacturer should not deviate from the requirements of this regulation. FDA must first have the opportunity to ensure that the manufacturer has established that an exemption or variance is warranted, to carry out its obligation of ensuring that devices are safe and effective.

13. Several comments stated that the proposed requirements are not necessary for all manufacturers, particularly small manufacturers with few employees and low-risk devices. Other comments stated that the documentation requirements are excessive.

FDA generally disagrees with these comments. The regulation provides the ''basic'' requirements for the design and manufacture of medical devices. And, as noted in the previous response, the requirements are written in general terms to allow manufacturers to establish procedures appropriate for their devices and operations. Also, as discussed above, a manufacturer need only comply with those requirements applicable to the operations in which he or she is engaged. However, because the regulation requirements are basic, they will apply in total to most manufacturers subject to the regulation. The extent of the documentation necessary to meet the regulation requirements may vary with the complexity of the design and manufacturing operations, the size of the firm, the importance of a process, and the risk associated with the failure of the device, among other factors. Small manufacturers may design acceptable quality systems that require a minimum of documentation and, where possible, may automate documentation. In many situations, documentation may be kept at a minimum by combining many of the recordkeeping requirements of the regulation, for example, the production SOP's, handling, and storage procedures. When manufacturers believe that the requirements are not necessary for their operations, they may petition for an exemption or variance from all or part of the regulation pursuant to section 520(f)(2) of the act.

In addition, FDA has added a variance provision in § 820.1(e)(2) under which the agency can initiate a variance when it is in the best interest of the public health. Under this provision, for instance, the agency may initiate and grant a variance to manufacturers of devices during times of product shortages, where the devices are needed by the public and may not otherwise be made available, if such manufacturers can adequately assure that the resulting devices are safe and effective. The agency envisions this provision as a bridge, providing a manufacturer with the time necessary to fulfill the requirements in the regulation while providing important and needed devices to the public. Thus, the variance would only be granted for a short period of time, and only while the devices remained necessary and in short supply. Under this provision, FDA will require a manufacturer to submit a plan detailing the action it is taking to assure the safety and effectiveness of the devices it manufactures and to meet the requirements of the regulation.

This agency initiated variance provision is in accordance with section 520(f) of the act which permits, but does not require, FDA to promulgate regulations governing the good manufacturing practices for devices and section 701(a) of the act (21 U.S.C. 371(a)), which permits FDA to promulgate regulations for the efficient enforcement of the act. Because the statute does not mandate that the agency establish any requirements for device CGMP's, the agency has the authority to determine that the manufacturers of certain devices need not follow every requirement of the regulation.

Further, the agency initiated variance provision is in keeping with the intent of Congress that FDA prevent hazardous devices from reaching the marketplace, H. Rept. 853, 94th Cong., 2d sess. 25–26 (1976), and the general intent of the act that the agency undertake to protect the public health. The agency will only initiate such a variance where the devices are needed and may not otherwise be made available, and the manufacturer can assure the agency that its procedures are likely to be adequate and that it is actively pursuing full compliance. The variances will only be in effect for a limited time.

Section 820.1(e) has been modified to include the above addition, to reflect the title change of the regulation, and to provide the most current address for the DSMA.

ii. Definitions (§ 820.3)

14. Several comments were received regarding the definition of ''complaint.'' Comments generally believed that the definition was unclear and could be interpreted to include routine service requests, communications from customers unrelated to the quality, safety, or effectiveness of the device, and internal communications.

FDA agrees with the comments in part and has modified the definition to make clear that a communication would be considered a ''complaint'' only if the communication alleged some deficiency related to the identity, quality, durability, reliability, safety, effectiveness, or performance of the device after it is released for distribution. The definition is now very similar to the definition used in ISO/CD 13485.

The regulation addresses service requests and in-house indications of dissatisfaction under § 820.100 *Corrective and preventive action.* This section requires manufacturers to establish procedures to identify quality problems and process the information received to detect and correct quality problems. Information generated in-house relating to quality problems should be documented and processed as part of this corrective and preventive action program.

With respect to service requests, § 820.200 *Servicing* states that a service report that represents an event which

must be reported to the FDA under part 803 or 804 (21 CFR part 803 or 804) shall automatically be considered a complaint. All other service reports must be analyzed for trends or systemic problems and when found, these trends or systemic problems must be investigated according to the provisions of § 820.100 *Corrective and preventive action*.

15. One comment suggested that the agency delete the phrase ''used during device manufacturing'' in the definition of ''component'' because it was confusing and may cause problems with certain aspects of distributor operations.

FDA agrees and has deleted the words ''used during device manufacturing'' from the definition because it was not intended to differentiate between distributors and manufacturers. Further, FDA deleted the term ''packaging'' to clarify that every piece of packaging is not necessarily a component. Only the materials that are part of the ''finished, packaged, and labeled device'' are considered to be components.

16. Several comments stated that the term ''complete history'' in the definition of ''control number'' should be clarified or deleted because it is unclear what a complete production history is, and the term could be construed to require full traceability for all component lots of any product containing a control number.

FDA agrees in part with the comments. The control number is the means by which the history of the device, from purchase of components and materials through distribution, may be traced, where traceability is required. The definition does not require that a manufacturer be able to trace the device whenever control numbers are used. In fact, the definition itself does not establish any requirements. The agency notes, however, that the manufacturer's traceability procedures should ensure that a complete history of the device, including environmental conditions which could cause the device to fail to conform to its specified requirements, can be traced and should facilitate investigation of quality problems and corrective action. FDA notes, however, that the level of detail required for this history is dependent on the nature of the device, its intended use, and its complexity. Therefore, FDA has removed the term ''complete'' in the definition for clarity and flexibility.

FDA has also amended the definition for added flexibility, to state that symbols may be used and has included the term ''unit'' for any device that is not manufactured as a lot or batch.

17. The definition of ''critical device'' has been deleted for the reasons discussed above.

18. Several comments stated that the term ''design history record'' should be changed because the acronym for the term is the same as that for device history record (the DHR). Other comments said the ''design history record'' should not need to contain documentation of a ''complete'' design history. One comment stated that the definition should allow reference to records containing the design history of the device. A few comments stated that the term should be deleted altogether because it is redundant with the definition of device master record (the DMR).

FDA agrees in part with these comments and has changed the term ''design history record'' to ''design history file.'' In addition, FDA has amended the provisions to require that the file describe the design history, as it may not be necessary to maintain a record of every step in the design phase, although the ''entire history'' should be apparent from the document. Section 820.30(j) further delineates what should be in the design history file (the DHF), specifically records sufficient to verify that the design was developed in accordance with the design and development plan and other applicable design requirements of the regulation.

FDA does not agree that the definitions of the DHF and the DMR are redundant. The DHF for each type of device should include, for example, the design and development plan, design review results, design verification results, and design validation results, as well as any other data necessary to establish compliance with the design requirements. The DMR should contain all of the procedures related to each type of device as required by this part and the most current manufacturing specifications of the device, once the design specifications have been transferred into production.

19. One comment on ''design input'' stated it was confused by the term ''requirements'' and wanted to know whose requirements are encompassed in this definition.

The term ''requirement'' is meant in the broadest sense, to encompass any internally or externally imposed requirements such as safety, customer-related, and regulatory requirements. All of these requirements must be considered as design inputs. How these requirements are handled and dealt with is up to the manufacturer.

20. Two comments stated that the definition of ''design output'' should be revised because it is not necessary, and would be burdensome, to keep records of and review the ''results of a design effort at each design phase and at the end.'' Other comments suggested that the design output definition should be restricted to physical characteristics of the device.

FDA agrees in part, but has not deleted the phrase ''results of a design effort at each design phase and at the end'' from the definition. The intent was not to dictate when design phases would occur. Such phases will be defined in the design and development plan. For example, a manufacturer may only have a few design phases for a new type of syringe. Thus, design output would be the results of those few efforts. The results of each design phase constitute the total design output. The definition has been amended, however, to clarify that the finished design output is the basis for the DMR.

FDA disagrees with the comments that suggest that the design output should be restricted to physical characteristics of the device. Design output is more than just the device specifications. Design output includes, among other things, the specifications for the manufacturing process, the quality assurance testing, and the device labeling and packaging. It is important to note that the design effort should not only control the design aspects of the device during the original development phase, but also all subsequent design and development activities including any redesign or design changes after the original design is transferred to production.

21. A few comments on the definition of ''design review'' stated that proposing solutions to problems is not part of the design review activity. Two other comments expressed concern that the definition would require that *each design review be ''comprehensive.''*

In response to the comments on the proper role of design review, FDA agrees that the design review participants are typically not responsible for establishing solutions, although they may do so in many small operations. The definition has been amended, but FDA wants to make clear that although the design review participants need not propose solutions, they should ensure that solutions to any identified problems are adequate and implemented appropriately.

Regarding the scope of design review, each design review need not be ''comprehensive'' for the entire design process but must be ''comprehensive'' for the design phase being reviewed. However, at the end of the design process when the design is transferred

to production, all aspects of the design process should have been reviewed.

A few other changes were made to harmonize with the definition in ISO 8402:1994 ''Quality—Vocabulary.''

22. Comments on the definition of ''device master record'' pointed out that the definition is not consistent with the requirements of § 820.181 *Device master record*. Other comments stated that the definition should allow reference to records. One comment stated that ''all'' procedures related to a specific finished device need not be included in the DMR, such as the procedures for the design and development, since they may be in the DHF.

FDA agrees in part with the comments that found the DMR definition and requirements to be inconsistent and has amended the definition to be consistent with the requirements set forth in § 820.181. FDA does not believe, however, that it is necessary to modify the definition to include the referencing of records because the DMR requirements in § 820.181 state that the DMR ''shall include or refer to the location of'' the required information. FDA agrees that the term ''all'' is not necessary and has deleted it in order to give manufacturers the necessary flexibility.

23. The definition for the term ''end-of-life'' was added to the Working Draft because this term was used in the definitions for ''refurbisher'' and ''servicing'' to help distinguish the activities of refurbishing from those of servicing. FDA determined that such a distinction was necessary, due to comments and ongoing confusion regarding the difference between the two functions, and the different requirements applicable to the functions.

Many written comments and persons who testified at the August and September 1995 meetings stated that the term was confusing, unnecessary, and introduced many new legal and liability issues. FDA agrees with these comments and has deleted the term throughout the regulation. FDA has also deleted definitions for ''refurbisher'' and ''servicing'' for the reasons discussed below.

24. The few comments received on the definition of ''establish'' indicated a concern that the regulation requires too much documentation and is more onerous than ISO 9001 requirements.

FDA disagrees with the comments. The term ''establish'' is only used where documentation is necessary. FDA also notes that the quality system regulation is premised on the theory that adequate written procedures, which are implemented appropriately, will likely ensure the safety and effectiveness of the device. ISO 9001:1994 relies on the same premise. The 1994 version of ISO 9001 broadly requires the manufacturer to ''establish, document, and maintain a quality system,'' which includes documenting procedures to meet the requirements.

The definition has been amended, however, in response to general comments received, to clarify that a ''document'' may be in writing or on electronic media, to allow flexibility for any type of recorded media.

25. FDA received comments questioning the inclusion of a device that is intended to be sterile, but that is not yet sterile, in the definition of ''finished device.'' A few comments stated that ''capable of functioning'' is ambiguous, and ''suitable for use'' is not necessary. Another comment requested that the term ''accessory'' be defined.

FDA disagrees with the comments, but has amended the definition for clarification. Since the 1978 CGMP regulation was promulgated, FDA has been repeatedly asked whether devices intended to be sold as sterile are considered subject to the CGMP requirements, even though they have not yet been sterilized. The agency had intended the new definition to make explicit the application of the regulation to the manufacture of sterile devices that have yet to be sterilized. Although FDA believes it should be obvious that such devices are subject to CGMP requirements, some manufacturers have taken the position that the regulation does not apply because the device is not ''finished'' or ''suitable for use'' until it has been sterilized.

To better clarify its intent, FDA has amended the definition to add that all devices that are capable of functioning, including those devices that could be used even though they are not yet in their final form, are ''finished devices.'' For example, devices that have been manufactured or assembled, and need only to be sterilized, polished, inspected and tested, or packaged or labeled by a purchaser/manufacturer are clearly not components, but are now in a condition in which they could be used, therefore meeting the definition of ''finished device.''

The distinction between ''components'' and ''finished devices'' was *not* intended to permit manufacturers to manufacture devices without complying with CGMP requirements by claiming that other functions, such as sterilization, incoming inspection (where sold for subsequent minor polishing, sterilization, or packaging), or insertion of software, will take place. The public would not be adequately protected in such cases if a manufacturer could claim that a device was not a ''finished'' device subject to the CGMP regulation because it was not in its ''final'' form.

The phrase ''for commercial distribution'' was deleted from the proposed definition of ''finished device'' because it is not necessary for a device to be in commercial distribution to be considered a finished device. Further, FDA notes that the term ''accessory'' is described in § 807.20(a)(5) (21 CFR 807.20(a)(5)).

26. Two comments on the definition of ''lot or batch'' requested that the definition be clarified: One to reflect that single units may be produced for distribution, the other to indicate that what constitutes a lot or a batch may vary depending on the context.

In response to the comments, FDA has modified the definition to make clear that a lot or batch may, depending on circumstances, be comprised of one finished device. Whether for inspection or for distribution, a lot or batch is determined by the factors set forth in the definition; of course, a manufacturer may determine the size of the lot or batch, as appropriate.

27. Several comments received on the definition of ''executive management'' objected that the definition is inconsistent with ISO 9001. Others thought that FDA should better define the level of management the term was intended to describe.

FDA agrees with both concerns and has modified the definition by deleting the second half, which appeared to bring executive authority and responsibility too far down the organization chart. The term was intended to apply only to management that has the authority to bring about change in the quality system and the management of the quality system. Although such management would clearly have authority over, for example, distribution, those who may have delegated management authority over distribution would not necessarily have authority over the quality system and quality policy. Accordingly, the definition has been modified to include only those who have the authority and responsibility to establish and make changes to the quality policy and quality system. It is the responsibility of top management to establish and communicate the quality policy. In addition, the term ''executive management'' has been changed to ''management with executive responsibility,'' to harmonize with ISO 9001:1994.

28. Several comments in response to the proposed definition of

''manufacturer'' stated that refurbishers and servicers should be added to the definition of a ''manufacturer.'' Other comments recommended adding the term ''remanufacturer.'' Other comments requested deletion of contract sterilizers, installers, specification developers, repackagers, relabelers, and initial distributors from the definition. One comment stated that the phrase ''processes a finished device'' should be explained in the definition of manufacturer.

FDA's Compliance Policy Guide (CPG) 7124.28 contains the agency's policy regarding the provisions of the act and regulations with which persons who recondition or rebuild used devices are expected to comply. This CPG is in the process of being revised in light of FDA's experience in this area. FDA is not including the terms ''servicer'' or ''refurbisher,'' as they relate to entities outside the control of the original equipment manufacturer, in this final regulation, even though it believes that persons who perform such functions meet the definition of manufacturer. Because of a number of competitive and other issues, including sharply divided views by members of the GMP Advisory Committee at the September 1995 meeting, FDA has elected to address application of the CGMP requirements to persons who perform servicing and refurbishing functions outside the control of the original manufacturer in a separate rulemaking later this year, with another opportunity for public comment.

FDA agrees that the term ''remanufacturing'' should be added to the definition of ''manufacturer'' and has separately defined the term. A remanufacturer is defined as ''any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.''

However, FDA disagrees that contract sterilizers, installers, specification developers, repackagers, relabelers, and initial distributors should be deleted from the definition, primarily because all such persons may have a significant effect on the safety and effectiveness of a device and on the public health. All persons who perform these functions meet the definition of manufacturer, and therefore should be inspected to ensure that they are complying with the applicable provisions. For example, a specification developer initiates the design requirements for a device that is manufactured by a second party for subsequent commercial distribution. Such a developer is subject to design controls. Further, those that perform the functions of contract sterilization, installation, relabeling, remanufacturing, and repacking have routinely been considered to be manufacturers under the original CGMP definition, and the agency has treated them as such by inspecting them to ensure that they comply with the appropriate portions of the original CGMP. By explicitly including them in the definition of ''manufacturer'' the agency has simply codified its longstanding policy and interpretation of the original regulation.

The phrase ''processes a finished device'' applies to a finished device *after* distribution. Again, this phrase has been part of the CGMP regulation definition of ''manufacturer'' for 18 years.

29. A number of comments on the definition of ''manufacturing material,'' and on other parts of the proposal containing requirements for ''manufacturing material,'' stated that while the control of manufacturing material is important, it need not be as extensive as required throughout the regulation. Other comments stated that the meaning of the phrase ''or other byproducts of the manufacturing process'' is unclear, and should be deleted. One comment suggested that the definition be modified to separate the definition from the examples.

FDA agrees that, depending on the manufacturing material and the device, the degree of control that is needed will vary. FDA believes that manufacturing materials must be assessed, found acceptable for use, and controlled. Therefore, the regulation requires manufacturers to assess, assure acceptability of, and control manufacturing materials to the degree necessary to meet the specified requirements. The agency notes that international standards such as ISO 8402:1994 include manufacturing material in their definition of ''product,'' to which all requirements apply, and notes that FDA has added the same definition in § 820.3(r) in its effort toward harmonization.

FDA amended the definition of manufacturing material to read ''a concomitant constituent, or a byproduct constituent produced during the manufacturing process'' to help clarify this definition. These terms refer to those materials or substances that naturally occur as a part of the material or during the manufacturing process which are intended to be removed or reduced in the finished device. For example, some components, such as natural rubber latex, contain allergenic proteins that must be reduced or removed from the finished devices. The definition has been modified to include ''concomitant constituents'' to clarify the meaning.

In addition to clarifying the definition, FDA has deleted the specific examples. Therefore, FDA notes that cleaning agents, mold release agents, lubricating oils, latex proteins, and sterilant residues are just some examples of manufacturing materials.

30. The comments received on the definition for ''nonconforming'' conveyed a general sense that the definition was confusing, with various comments suggesting that different parts of the definition should be deleted and one suggesting that the definition be deleted altogether.

In response to these comments, the definition of ''nonconforming'' has been deleted. However, the definition from ISO 8402:1994 for ''nonconformity'' was added to ensure that the requirements in the regulation, especially those in §§ 820.90 *Nonconforming product* and 820.100 *Corrective and preventive action* are understood. FDA emphasizes that a ''nonconformity'' may not always rise to the level of a product defect or failure, but a product defect or failure will typically constitute a nonconformity.

31. Several comments requested various revisions to the definition of ''production'' to make it more clear, and one thought that it was a common term and should be deleted.

In response, FDA has deleted the definition for ''production'' because it should be commonly understood.

As noted in response to comments on the definition of manufacturing material, FDA has added a definition of ''product'' to conform to the definition in ISO 8402:1994 and to avoid the necessity of repeating the individual terms throughout the regulation. Whenever a requirement is not applicable to all types of product, the regulation specifically states the product(s) to which the requirement is applicable.

It should be noted that the regulation has acceptance requirements for incoming ''product'' and other requirements for ''product,'' which by definition includes manufacturing materials. Manufacturing materials should be controlled in a manner that is commensurate with their risk as discussed above. However, for manufacturing materials that are ''concomitant constituents,'' FDA realizes that incoming acceptance, identification, etc., may not be feasible. The important control measure for ''concomitant constituents'' is the

reduction or removal requirement found in § 820.70(h).

32. A few comments stated that the definition of ''quality'' should be changed to be identical to ISO 8402. Others stated that the terminology adopted from ISO 8402, ''that bear on,'' is too broad and could cover every potential and imaginable factor. Still others wanted to add the phrase, ''as defined by the manufacturer'' to the end of the sentence.

FDA disagrees with the comments and believes that the definition is closely harmonized to that in ISO 8402:1994. FDA believes that the definition appropriately defines quality in the context of a medical device and believes that the phrase from ISO 8402:1994, ''stated and implied needs,'' has the same meaning as the phrase ''fitness-for-use, including safety and performance'' in the context of the Quality System regulation. Further, ''quality'' is not just ''defined by the manufacturer'' but is also defined by customer need and expectation.

33. Many comments received on the ''quality audit'' definition suggested that the definition should not state that it is an examination of the ''entire'' quality system because that would require that every audit include the ''entire'' quality system. Other comments on ''quality audit'' stated that it is unclear what is meant by the last sentence of the proposed definition, namely, that '' '[q]uality audit' is different from * * * other quality system activities required by or under this part.''

FDA agrees that while the quality audit is an audit of the ''entire'' quality system, audits may be conducted in phases, with some areas requiring more frequent audits than other areas, and that each audit need not review the whole system. The frequency of internal quality audits should be commensurate with, among other things, the importance of the activity, the difficulty of the activity to perform, and the problems found. To avoid any misunderstanding, the word ''entire'' before quality system has been deleted.

FDA emphasizes that if conducted properly, internal quality audits can prevent major problems from developing and provide a foundation for the management review required by § 820.20(c), ''Management review.''

In response to the confusion about the last sentence of the proposed definition, FDA has deleted the last sentence. The purpose of the sentence was to clarify that the internal audit requirement is different from, and in addition to, the requirements for establishing quality assurance procedures and recording results. On occasion, manufacturers have attempted to prevent FDA investigators from reviewing such quality assurance procedures and results (for example, trend analysis results) by stating that they are part of the internal quality audit report and not subject to review during a CGMP inspection. FDA disagrees with this position. To clarify which records are exempt from routine FDA inspection, FDA has added § 820.180(c).

34. One comment said that the word ''executive'' should be deleted from the definition of ''quality policy'' because quality policy should be supported by all personnel, not just those in executive management. A few comments stated that ''formally expressed'' should be deleted because it is incompatible with the requirements in § 820.20(a) and (c) which require that the quality policy be ''established.'' Other comments stated that the ''quality'' before ''intentions'' was tautological.

FDA agrees that all company personnel must follow the quality policy. However, the definition is intended to make clear that the quality policy must be established by top management. Therefore it has been retained. The term ''executive management'' has been modified to ''management with executive responsibility'' to be consistent with the revised ISO 9001:1994. FDA agrees with the remaining comments and has changed ''formally expressed'' to ''established'' for consistency and has deleted the ''quality'' before ''intentions.''

35. A few comments suggested using the definition of ''quality systems'' from ISO 8402 and 9001. Other comments on the definition of ''quality system'' said that the term ''quality management'' should be defined.

FDA agrees in part with the comments. The term ''specifications'' has been deleted to harmonize the definition with ISO 8402:1994. FDA does not agree that the term ''quality management'' must be defined. A definition can be found in ISO 8402:1994 that is consistent with FDA's use of the term.

36. Many comments on the definition of ''record'' were received. Some thought the term was too broad, giving FDA access to all documents and exceeding FDA's inspection authority. Others thought that the definition of ''record'' would tremendously increase the recordkeeping burden. Several comments recommended that FDA adopt the ISO definition.

The definition of ''record'' was deleted because it seemed to add more confusion than clarity. The definition was intended to clarify that ''records'' may include more than the traditional hardcopy procedures and SOP's, for example, plans, notes, forms, data, etc. FDA was trying to clarify that ''records'' could be written, electronic, optical, etc., as long as they could be stored and controlled. FDA could not adopt the ISO 8402:1994 definition because of how the term ''record'' is used in the act, which is broader than the ISO definition. Therefore, FDA will allow the act and case law to continue to define the term.

37. The definition in the Working Draft of ''refurbisher'' was deleted and will be addressed in the separate rulemaking described above.

38. FDA added the definition of ''remanufacturer'' to codify FDA's longstanding policy and interpretation of the original CGMP. The language is consistent with the 510(k) provisions and the premarket approval amendment/supplement requirements, because FDA has always considered remanufacturers in fact to be manufacturers of a new device.

39. Several comments on the definition of ''reprocessing'' requested clarification of the difference between that term and ''refurbishing.'' Several other comments on the definition of ''reprocessing'' stated that FDA should clarify that ''reprocessing'' is an activity performed before a device is distributed. Others commented that the term ''rework'' should be used instead of the term ''reprocessing,'' to be consistent with ISO terminology.

FDA agrees with the comments and has changed the term to ''rework,'' adopted the ISO 8402:1994 definition, and added that ''rework'' is performed according to specified DMR requirements before the device is released for distribution.

40. A few comments stated that including the term ''maintenance'' in the proposed definition of ''servicing'' implies that preventative maintenance would be subject to the regulation. Other comments said that it may not be desirable to return old devices or devices that have received field modifications to the original specifications. Therefore, the comments suggested deleting the last part of the definition that states that ''servicing'' is returning a device to its specifications.

FDA has deleted the definition of ''servicing'' and has not added a definition of ''servicer'' because this will be covered in the separate rulemaking discussed above. FDA notes, however, that servicing performed by manufacturers and remanufacturers is subject to the requirements in § 820.200 *Servicing.* These requirements are a codification of longstanding interpretations of the original CGMP,

§ 820.20(a)(3), and current agency policy.

41. Several comments were received on the proposed definition of ''special process.'' Many asked for clarification or adoption of the ISO definition. Some stated that it is impossible to completely verify processes in every instance.

FDA has deleted the definition because the term ''special process'' is no longer used in ISO 9001:1994, except in a note. FDA has, however, modified the requirements of the regulation to reflect that, in many cases, testing and inspecting alone may be insufficient to prove the adequacy of a process. One of the principles on which the quality systems regulation is based is that all processes require some degree of qualification, verification, or validation, and manufacturers should not rely solely on inspection and testing to ensure processes are adequate for their intended uses.

42. Several comments on the definition of ''specification'' suggested that the term should not apply to quality system requirements. One comment suggested that the phrase ''other activity'' be deleted because it is too broad. Another comment noted that the definition in ISO 9001 pertains to requirements, not only documents.

In response, FDA has amended the definition to make clear that it applies to the requirements for a product, process, service, or other activity. The reference to the quality system has been deleted. FDA disagrees that the definition is too broad and has not deleted the term ''other activity'' because a specification can be developed for anything the manufacturer chooses. FDA notes, however, that ISO 9001:1994 does not contain a definition for ''specification'' but uses the definition found in ISO 8402:1994.

43. Numerous comments were received on the definitions of ''validation'' and ''verification.'' Almost all stated that the two definitions overlapped and that there was a need to rewrite the definitions to prevent confusion. Many suggested that the ISO definitions be adopted. Others stated that there was a need to distinguish between design validation and process validation.

FDA agrees with the comments and has rewritten the two definitions to better reflect the agency's intent. FDA has adopted the ISO 8402:1994 definition of validation. ''Validation'' is a step beyond verification to ensure the user needs and intended uses can be fulfilled on a consistent basis. FDA has further distinguished ''process validation'' from ''design validation'' to help clarify these two types of ''validation.'' The ''process validation'' definition follows from FDA's ''Guidelines on General Principles of Process Validation'' (Ref. 10). The definition for ''design validation'' is consistent with the requirements contained in § 820.30 *Design controls.*

The ISO 8402:1994 definition of ''verification'' has been adopted. ''Verification'' is confirmation by examination and provision of objective evidence that specified requirements for a particular device or activity at hand have been met.

iii. Quality System (§ 820.5)

44. Several comments suggested that the requirement should be more general, in that the requirement that devices be safe and effective is covered elsewhere in the regulation. The comments recommended that the quality system requirements be harmonized with international standards and focus on requiring that a system be established that is appropriate to the specific device and that meets the requirements of the regulation.

FDA agrees in part with the comments and has modified the language as generally suggested by several comments to require that the quality system be ''appropriate for the specific medical device(s) designed or manufactured, and [] meet[] the requirements of this part.'' This is essentially the requirement of the original CGMP regulation with the added reference to design control.

The requirements that effective quality system instructions and procedures be established and effectively maintained are retained; however, they were moved to § 820.20(b)(3)(i). As previously noted, the quality system regulation is premised on the theory that the development, implementation, and maintenance of procedures designed to carry out the requirements will assure the safety and effectiveness of devices. Thus, the broad requirements in § 820.5 are in a sense the foundation on which the remaining quality system requirements are built.

B. Quality System Requirements (Subpart B)

i. Management Responsibility (§ 820.20)

45. Several comments on § 820.20(a), ''Quality policy,'' related to the use of the term ''executive management.'' A few comments stated that quality system development and implementation are the responsibility of the chief executive officer, but how he or she chooses to discharge the responsibility should be left to the discretion of the manufacturer. Other comments stated that the requirement that executive management ensure that the quality policy is understood is impossible and should be deleted or rewritten.

FDA agrees in part with the comments. In response to the comments, FDA has deleted the term ''executive management'' and replaced it with ''management with executive responsibility,'' which is consistent with ISO 9001:1994. Management with executive responsibility is that level of management that has the authority to establish and make changes to the company quality policy. The establishment of quality objectives, the translation of such objectives into actual methods and procedures, and the implementation of the quality system may be delegated. The regulation does not prohibit the delegation. However, it is the responsibility of the highest level of management to establish the quality policy and to ensure that it is followed. (See *United States* v. *Dotterweich,* 320 U.S. 277 (1943), and *United States* v. *Park,* 421 U.S. 658 (1975).)

For this reason, FDA disagrees that the requirement that management ensure that the quality policy is understood should be deleted. It is without question management's responsibility to undertake appropriate actions to ensure that employees understand management's policies and objectives. Understanding is a learning process achieved through training and reinforcement. Management reinforces understanding of policies and objectives by demonstrating a commitment to the quality system visibly and actively on a continuous basis. Such commitment can be demonstrated by providing adequate resources and training to support quality system development and implementation. In the interest of harmonization, the regulation has been amended to be very similar to ISO 9001:1994.

46. A few comments stated that the words ''adequate'' and ''sufficient'' should be deleted from § 820.20(b) ''Organization,'' as they are subjective and too difficult to define. One comment thought that the general requirements in the paragraphs are addressed by § 820.25 *Personnel.* Another comment stated that ''designed'' should be added prior to ''produced'' for consistency with the scope.

FDA agrees that the requirement for ''sufficient personnel'' is covered in §§ 820.20(b)(2), ''Resources,'' and 820.25 *Personnel,* both of which require manufacturers to employ sufficient personnel with the training and

experience necessary to carry out their assigned activities properly. The phrase is, therefore, deleted. However, FDA has retained the requirement for establishing an ''adequate organizational structure'' to ensure compliance with the regulation, because such an organizational structure is fundamental to a manufacturer's ability to produce safe and effective devices. The organizational structure should ensure that the technical, administrative, and human factors functions affecting the quality of the device will be controlled, whether these functions involve hardware, software, processed materials, or services. All such control should be oriented towards the reduction, elimination, or ideally, prevention of quality nonconformities. Further, the agency does not believe that the term is ambiguous. The organizational structure established will be determined in part by the type of device produced, the manufacturer's organizational goals, and the expectations and needs of customers. What may be an ''adequate'' organizational structure for manufacturing a relatively simple device may not be ''adequate'' for the production of a more complex device, such as a defibrillator. FDA has also added ''designed'' prior to ''produced'' to be consistent with the scope of the regulation.

47. A number of comments on proposed § 820.20 (b)(1)(i) through (b)(1)(v), ''Responsibility and authority,'' objected to the section, stating that it was too detailed and confusing and that the wording was redundant with other sections of the proposal.

FDA agrees generally with the comments in that the proposed paragraphs set forth examples of situations in which independence and authority are important. Therefore, the examples provided in § 820.20 (b)(1)(i) through (b)(1)(v) are deleted. However, FDA has retained the broad requirement that the necessary independence and authority be provided as appropriate to every function affecting quality. FDA emphasizes that it is crucial to the success of the quality system for the manufacturer to ensure that responsibility, authority, and organizational freedom (or independence) is provided to those who initiate action to prevent nonconformities, identify and document quality problems, initiate, recommend, provide, and verify solutions to quality problems, and direct or control further processing, delivery, or installation of nonconforming product. Organizational freedom or independence does not necessarily require a stand-alone group, but responsibility, authority, and independence should be sufficient to attain the assigned quality objectives with the desired efficiency.

48. Several comments on proposed § 820.20(b)(2), ''Verification resources and personnel,'' stated that requiring ''adequately'' trained personnel was subjective and that the section was not consistent with ISO 9001.

FDA agrees that the section is not consistent with ISO 9001, and has adopted the language used in ISO 9001:1994, section 4.1.2.2, ''Resources,'' and has renamed the section ''Resources.'' The provision is now a broad requirement that the manufacturer provide adequate resources for the quality system and is not restricted to the verification function. FDA acknowledges that § 820.25(a), ''General,'' requires that sufficiently trained personnel be employed. However, § 820.20(b)(2), ''Resources,'' emphasizes that *all* resource needs must be provided for, including monetary, supplies, etc., as well as personnel resources. In contrast, § 820.25(a) specifically addresses education, background, training, and experience requirements for personnel.

49. Comments on § 820.20(b)(3), ''Management representative,'' stated that the management representative should not be limited to ''executive'' management. A few comments stated that the appointment should be documented. In addition, a few comments from proposed § 820.5 stated that the terms ''effective'' and ''effectively'' should be defined.

The agency agrees that the responsibility need not be assigned to ''executive'' management and has modified the requirement to allow management with executive responsibility to appoint a member of management. When a member of management is appointed to this function, potential conflicts of interest should be examined to ensure that the effectiveness of the quality system is not compromised. In addition, in response to many comments, the requirement was amended to make clear that the appointment of this person must be documented, moving the requirement up from § 820.20(b)(3)(ii). The amended language is consistent with ISO 9001:1994. Further, FDA has amended this section to change ''executive management'' to ''management with executive responsibility'' for consistency with the definition.

The terms ''effective'' and ''effectively'' are no longer used in § 820.5 but ''effectively'' is found in § 820.20(b)(3)(i). FDA does not believe that these terms require a definition. Instructions and procedures must be defined, documented, implemented, and maintained in such a way that the requirements of this part are met. If they are, they will be ''effective.''

50. A few comments stated that the improvement of the quality system is not a requirement under the act and the reference to such improvement in § 820.20(b)(3)(ii) should, therefore, be deleted.

FDA agrees in part with the comments and has deleted the requirement that the person appointed under this section provide information for improving the quality system. The provision implied that the manufacturer must go beyond the requirements of the regulation. FDA notes, however, that information collected in complying with §§ 820.20(b)(3)(ii) and 820.100 *Corrective and preventive action,* should be used not only for detecting deficiencies and for subsequent correction of the deficiencies but also to improve the device and quality system.

51. Many comments stated that the report required by § 820.20(c), ''Management review,'' should not be subject to FDA review, due to the same liability and self-incrimination concerns related to the internal audit.

FDA agrees in part with the comments. The proposed regulation did not state FDA's intentions with respect to inspectional review of the results of the required management review. After careful consideration of the comments, FDA agrees that it will not request to inspect and copy the reports of reviews required by § 820.20(c) when conducting routine inspections to determine compliance with this part. FDA believes that refraining from routinely reviewing these reports may help ensure that the audits are complete and candid and of maximum use to the manufacturer. However, FDA believes that it is important that the dates and results of quality system reviews be documented, and FDA may require that management with executive responsibility certify in writing that the manufacturer has complied with the requirements of § 820.20(c). FDA will also review the written procedures required by § 820.20(c), as well as all other records required under § 820.20.

52. A few comments stated that the management review should not be dictated by established review procedures because management level employees should be fully capable of reviewing documents without a written procedure.

As noted above, FDA has retained the requirement for establishing procedures to conduct the required management review in § 820.20(c). FDA believes that

a manufacturer can establish procedures flexible enough for management to vary the way in which a review is conducted, as appropriate. Procedures should require that the review be conducted at appropriate intervals and should be designed to ensure that all parts of the quality system are adequately reviewed. A manufacturer may, of course, develop procedures that permit review of different areas at different times, so long as such reviews are sufficient to carry out the objectives of this section. If there are known problems, for example, a ''sufficient frequency'' may be fairly frequent. Further, because FDA will not be reviewing the results of such reviews, FDA must be assured that this function will occur in a consistent manner.

53. A few comments stated that § 820.20(c) should be deleted because it duplicates the quality audit required by § 820.22.

FDA disagrees that § 820.20(c) duplicates the requirements in § 820.22. The purpose of the management reviews required by § 820.20(c) is to determine if the manufacturer's quality policy and quality objectives are being met, and to ensure the continued suitability and effectiveness of the quality system. An evaluation of the findings of internal and supplier audits should be included in the § 820.20(c) evaluation. The management review may include a review of the following: (1) The organizational structure, including the adequacy of staffing and resources; (2) the quality of the finished device in relation to the quality objectives; (3) combined information based on purchaser feedback, internal feedback (such as results of internal audits), process performance, product (including servicing) performance, among other things; and (4) internal audit results and corrective and preventive actions taken. Management reviews should include considerations for updating the quality system in relation to changes brought about by new technologies, quality concepts, market strategies, and other social or environmental conditions. Management should also review periodically the appropriateness of the review frequency, based on the findings of previous reviews. The quality system review process in § 820.20(c), and the reasons for the review, should be understood by the organization.

The requirements under § 820.22 *Quality audit* are for an internal audit and review of the quality system to verify compliance with the quality system regulation. The review and evaluations under § 820.22 are very focused. During the internal quality audit, the manufacturer should review all procedures to ensure adequacy and compliance with the regulation, and determine whether the procedures are being effectively implemented at all times. In contrast, as noted above, the management review under § 820.20(c) is a broader review of the organization as a whole to ensure that the quality policy is implemented and the quality objectives are met. The reviews of the quality policy and objectives (§ 820.20(c)) should be carried out by top management, and the review of supporting activities (§ 820.22) should be carried out by management with executive responsibility for quality and other appropriate members of management, utilizing competent personnel as decided on by the management.

54. Some comments suggested that the requirements in § 820.186(a) and (d) be moved to § 820.20 for clarity and to better align with the structure of ISO 9001:1994 and ISO/CD 13485.

FDA agrees and has moved the specific requirements from § 820.186 and rewritten them into new § 820.20 (d) and (e) for clarity, better organization, and closer harmonization. Therefore, § 820.20(d) is consistent with ISO 9001:1994, section 4.2.3, ''Quality planning,'' and § 820.20(e) is consistent with ISO 9001:1994, sections 4.2.1, ''General,'' and 4.2.2, ''Quality-system procedures.'' Section 820.20(e) discusses ''[a]n outline of the structure of the documentation used in the quality system.'' FDA believes that outlining the structure of the documentation is beneficial and, at times, may be critical to the effective operation of the quality system. FDA recognizes, however, that it may not be necessary to create an outline in all cases. For example, it may not be necessary for smaller manufacturers and manufacturers of less complicated devices. Thus, the outline is only required where appropriate.

ii. Quality Audit (§ 820.22)

55. A few comments suggested that FDA delete the requirement that persons conducting the audit be ''appropriately trained'' from the second sentence of proposed § 820.22(a), because it is subjective and not consistent with ISO 9001.

FDA has deleted the requirement from § 820.22(a) because § 820.25 *Personnel* requires that such individuals be appropriately trained. Further, FDA has attempted to better harmonize with ISO 9001:1994, which does not explicitly state personnel qualifications in each provision. Similarly, in response to general comments suggesting better harmonization, FDA has added the requirement that the audit ''determine the effectiveness of the quality system'' as required by ISO 9001:1994. This requirement underscores that the quality audit must not only determine whether the manufacturer's requirements are being carried out, but whether the requirements themselves are adequate.

56. Some comments stated that requiring ''individuals who do not have direct responsibility for the matters being audited'' to conduct the audits is impractical and burdensome, particularly for small manufacturers.

FDA disagrees with the comments. Both small and large manufacturers have been subject to the identical requirement since 1978 and FDA knows of no hardship, on small or large manufacturers, as a result. Small manufacturers must generally establish independence, even if it means hiring outside auditors, because the failure to have an independent auditor could result in an ineffective audit.

Manufacturers must realize that conducting effective quality audits is crucial. Without the feedback provided by the quality audit and other information sources, such as complaints and service records, manufacturers operate in an open loop system with no assurance that the process used to design and produce devices is operating in a state of control. ISO 9001:1994 has the same requirement for independence from the activity being audited.

57. Several comments claimed that the last sentence in proposed § 820.22(a), which required that followup corrective action be documented in the audit report, made no sense. The comments said that corrective action would be the subject of a followup report.

It was the agency's intent that the provision require that where corrective action was necessary, it would be taken and documented in a reaudit report. The provision has been rewritten to make that clear. New § 824.22 also clarifies that a reaudit is not always required, but where it is indicated, it must be conducted. The report should verify that corrective action was implemented and effective. Because FDA does not review these reports, the date on which the audit and reaudit were performed must be documented and will be subject to FDA review. The revised reaudit provision is consistent with ISO 9001:1994.

58. Many comments were received on proposed § 820.22(b) regarding the reports exempt from FDA review. Most of the comments objected to FDA reviewing evaluations of suppliers. FDA has decided not to review such

evaluations at this time and will revisit this decision after the agency gains sufficient experience with the new requirement to determine its effectiveness. A thorough response to the comments is found with the agency's response to other comments received on § 820.50 *Purchasing controls.* FDA has moved the section regarding which reports the agency will refrain from reviewing from § 820.22(b) to new § 820.180(c), ''Exemptions,'' under the related records requirements. FDA believes this organization is easier to follow.

iii. Personnel (§ 820.25)

59. A few comments stated that the requirement in § 820.25 *Personnel* for the manufacturer to employ ''sufficient'' personnel should be deleted, because whether there are ''sufficient'' personnel is a subjective determination, and it is unnecessary to require it since the manufacturer will know how best to staff the organization. A few other comments stated that the provision should not base the personnel requirements on ensuring that the requirements of the regulation are ''correctly'' performed, because no manufacturer can ensure that all activities are performed correctly. Another comment stated that the term ''employ'' should be changed because personnel may include qualified temporaries, contractors, and others who may not typically be considered ''employees.''

FDA disagrees with the suggestions that the terms ''sufficient'' and ''correctly'' be deleted. Whether ''sufficient'' personnel are employed will be determined by the requirements of the quality system, which must be designed to ensure that the requirements of the regulation are properly implemented. In making staffing decisions, a manufacturer must ensure that persons assigned to particular functions are properly equipped and possess the necessary education, background, training, and experience to perform their functions correctly. However, FDA changed ''ensure'' to ''assure'' to address the concerns that people do make mistakes and management cannot guarantee that work is correctly performed all of the time. Further, FDA agrees that the manufacturer must determine for itself what constitutes ''sufficient'' personnel with proper qualification in the first instance. However, if the manufacturer does not employ sufficient personnel, or personnel with the necessary qualifications to carry out their functions, the manufacturer will be in violation of the regulation. FDA has often found that the failure to comply with this requirement leads to other significant regulatory violations. FDA agrees with the comment that the term ''employ'' should be deleted so that the requirement covers all personnel who work at a firm.

60. In § 820.25(b), ''Training,'' FDA deleted the requirement that employees be trained ''by qualified individuals,'' because § 820.25(a) requires this. Several comments stated that FDA should add the requirement that the training procedure include the identification of training needs, to be consistent with the requirements in ISO 9001:1994 and ISO/CD 13485. Other comments stated that personnel need not be trained to the extent that they can quote chapter and verse of the regulation as long as they can adequately perform their assigned responsibilities. Several comments suggested deleting the requirements in the last two sentences in favor of a broad, general requirement that personnel be trained. A few comments stated that the last two sentences should be retained because they are crucial and sound requirements but that validation activities should be included with verification activities.

FDA amended the requirement so that the training procedure includes the identification of training needs. FDA deleted the requirement on understanding the CGMP requirements applicable to job functions to avoid the perception that personnel would need to know ''chapter and verse of the regulation.'' FDA notes, however, that a training program to ensure personnel adequately perform their assigned responsibilities should include information about the CGMP requirements and how particular job functions relate to the overall quality system. FDA further believes that it is imperative that training cover the consequences of improper performance so that personnel will be apprised of defects that they should look for, as well as be aware of the effect their actions can have on the safety and effectiveness of the device. In addition, FDA disagrees with comments that suggested that only ''personnel affecting quality'' should be required to be adequately trained. In order for the full quality system to function as intended, all personnel should be properly trained. Each function in the manufacture of a medical device must be viewed as integral to all other functions. FDA has reorganized the last two sentences, however, to place the requirements under § 820.25(b), ''Training,'' and has added validation activities as suggested by the comments.

61. Many comments objected to the proposed requirements of § 820.25(c), ''Consultants,'' stating that requiring a manufacturer to chose consultants that have sufficient qualifications and to keep records subject to FDA review of all consultants used, along with copies of their resumes and lists of previous jobs, would unreasonably interfere with the manufacturer's business activities and restrict the right of a manufacturer to hire consultants on any basis it chooses. Other comments said that a manufacturer's employment of a consultant has the same potential impact on the safety and effectiveness of medical devices as employment of any other contractor for services, and that consultants should, therefore, be covered by § 820.50 *Purchasing controls.*

FDA agrees in part with these comments. Although employing a consultant is a business decision, when a manufacturer hires consultants who do not have appropriate credentials, and manufacturing decisions are made based on erroneous or ill-conceived advice, the public suffers. Of course, the manufacturer is still ultimately responsible for following the CGMP requirements and will bear the consequences of a failure to comply. FDA notes that the use of unqualified consultants has led to regulatory action for the failure to comply with the CGMP regulation in the past. Thus, because of the significant impact a consultant can have on the safety and effectiveness of a device, FDA believes that some degree of control is required in the regulation.

The requirements are revised somewhat in response to comments, however, to reflect that it is not FDA's goal to dictate whom a manufacturer may use as a consultant, but instead to require that a manufacturer determine what it needs to adequately carry out the requirements of the regulation and to assess whether the consultant can adequately meet those needs. The requirements related to consultants have been added in § 820.50 *Purchasing controls* because a consultant is a supplier of a service.

C. Design Controls (Subpart C)

Since early 1984, FDA has identified lack of design controls as one of the major causes of device recalls. The intrinsic quality of devices, including their safety and effectiveness, is established during the design phase. Thus, FDA believes that unless appropriate design controls are observed during preproduction stages of development, a finished device may be neither safe nor effective for its intended use. The SMDA provided FDA with the

authority to add preproduction design controls to the device CGMP regulation. Based on its experience with administering the original CGMP regulation, which did not include preproduction design controls, the agency was concerned that the original regulation provided less than an adequate level of assurance that devices would be safe and effective. Therefore, FDA has added general requirements for design controls to the device CGMP regulation for all class III and II devices and certain class I devices. FDA is not subjecting the majority of class I devices to design controls because FDA does not believe that such controls are necessary to ensure that such devices are safe and effective and otherwise in compliance with the act. However, all devices, including class I devices exempt from design controls, must be properly transferred to production in order to comply with § 820.181, as well as other applicable requirements. For most class I devices, FDA believes that the production and other controls in the new quality system regulation and other general controls of the act will be sufficient, as they have been in the past, to ensure safety and effectiveness.

62. Many comments were submitted in response to the addition of design control requirements in general, many questioning how these new requirements would be implemented and enforced. For instance, several comments stated that the design control requirements do not reflect how medical devices are actually developed, because the concept of a design rarely originates with the manufacturer, who may not become involved until relatively late in the design evolution. Others expressed concern that FDA investigators will second-guess design issues in which they are not educated or trained, and stated that investigators should not debate whether medical device designs are ''safe and effective.''

FDA agrees in part with the comments. The design control requirements are not intended to apply to the development of concepts and feasibility studies. However, once it is decided that a design will be developed, a plan must be established to determine the adequacy of the design requirements and to ensure that the design that will eventually be released to production meets the approved requirements.

Those who design medical devices must be aware of the design control requirements in the regulation and comply with them. Unsafe and ineffective devices are often the result of informal development that does not ensure the proper establishment and assessment of design requirements which are necessary to develop a medical device that is safe and effective for the intended use of the device and that meets the needs of the user.

However, FDA investigators will not inspect a device under the design control requirements to determine whether the design is appropriate or ''safe and effective.'' Section 520(f)(1)(a) of the act precludes FDA from evaluating the ''safety or effectiveness of a device'' through preproduction design control procedures. FDA investigators will evaluate the process, the methods, and the procedures that a manufacturer has established to implement the requirements for design controls. If, based on any information gained during an inspection, an investigator believes that distributed devices are unsafe or ineffective, the investigator has an obligation to report the observations to the Center for Devices and Radiological Health (CDRH).

63. Several comments expressed concern that the application of design controls would severely restrict the creativity and innovation of the design process and suggested that design controls should not apply too early in the design development process.

FDA disagrees with the comments. It is not the intent of FDA to interfere with creativity and innovation, and it is not the intent of FDA to apply the design control requirements to the research phase. Instead, the regulation requires the establishment of procedures to ensure that whatever design is ultimately transferred to production is, in fact, a design that will translate into a device that properly performs according to its intended use and user needs.

To assist FDA in applying the regulation, manufacturers should document the flow of the design process so that it is clear to the FDA investigator where research is ending and development of the design is beginning.

64. A few comments stated that design controls should not be retroactive and that ongoing design development should be exempted.

FDA agrees in part with the comments. FDA did not intend the design requirements to be retroactive, and § 820.30 *Design controls* will not require the manufacturer to apply such requirements to already distributed devices. When the regulation becomes effective on June 1, 1997, it will apply to designs that are in the design and development phase, and manufacturers will be expected to have the design and development plan established. The manufacturer should identify what stage a design is in for each device and will be expected to comply with the established design and development plan and the applicable paragraphs of § 820.30 from that point forward to completion. If a manufacturer had a design in the *development stage* before June 1, 1997, and cannot comply with any particular paragraph of § 820.30, the manufacturer must provide a detailed justification as to why such compliance is not possible. However, designs will not have to be recycled through previous phases that have been completed. Manufacturers will be expected to comply in full by June 1, 1998. As stated earlier, FDA wants to emphasize that *it expects manufacturers to be in a reasonable state of compliance with the design control requirements from June 1, 1997, to June 1, 1998, because extra time was given to the industry for implementing design controls before the final regulation became effective.*

When changes are made to new or existing designs, the design controls of § 820.30 must be followed to ensure that the changes are appropriate and that the device will continue to perform as intended. FDA notes that the original CGMP regulation contained requirements for specification controls and controls for specification or design changes under § 820.100(a).

65. One comment asked how the proposed design controls would apply to investigational device exemption (IDE) devices, since devices under approved IDE's have been exempt from the CGMP regulation. Some comments suggested that any changes to the IDE regulation should be done in a separate rulemaking. Other comments stated that any change to the IDE regulation should be worded so that all of § 820.30 applies since the IDE process is supplying information in support of the design validation requirements but that all design requirements need not be completed prior to the start of the IDE because the clinical evaluation process often brings valuable information to the design project which may need to be incorporated into the design before design transfer.

The IDE regulation was published in 1976 and last updated in 1978, and has been in effect since that time. Devices being evaluated under IDE's were exempted from the original CGMP regulation because it was believed that it was not reasonable to expect sponsors of clinical investigations to ensure compliance with CGMP's for devices that may never be approved for commercial distribution. However, sponsors of IDE studies were required to ensure that investigational devices were manufactured under a state of control.

With respect to the new regulation, FDA believes that it is reasonable to expect manufacturers who design medical devices to develop the designs in conformance with design control requirements and that adhering to such requirements is necessary to adequately protect the public from potentially harmful devices. The design control requirements are basic controls needed to ensure that the device being designed will perform as intended when produced for commercial distribution. Clinical evaluation is an important aspect of the design verification and validation process during the design and development of the device. Because some of the device design occurs during the IDE stage, it is logical that manufacturers who intend to commercially produce the device follow design control procedures. Were a manufacturer to wait until all the IDE studies were complete, it would be too late to take advantage of the design control process, and the manufacturer would not be able to fulfill the requirements of the quality system regulation for that device.

Therefore, FDA has concurrently amended the IDE regulation,

812.1 Scope to state:

(a) * * * An IDE approved under § 812.30 or considered approved under § 812.2(b) exempts a device from the requirements of the following sections of the Federal Food, Drug, and Cosmetic Act (the act) and regulations issued thereunder: * * * good manufacturing practice requirements under section 520(f) *except for the requirements found in § 820.30, if applicable* (unless the sponsor states an intention to comply with these requirements under § 812.20(b)(3) or § 812.140(b)(4)(v)) and color additive requirements under section 721. (Emphasis added.)

FDA does not expect any new information in IDE applications as a result of this amendment, nor will FDA inspect design controls during bioresearch monitoring inspections. FDA is simply making a conforming amendment to the IDE regulation to make clear that design controls must be followed when design functions are undertaken by manufacturers, including design activity which occurs under an approved IDE. FDA will evaluate the adequacy of manufacturers' compliance with design control requirements in routine CGMP inspections, including preapproval inspections for premarket approval applications (PMA's).

66. Many written comments and oral comments at the August and September 1995 meetings recommended that, because design controls are a major addition to the regulation, the effective date for design controls should be delayed until 18 months after publication of the final rule.

FDA has addressed these comments by extending the effective date of the regulation until June 1, 1997, and by the inspectional strategy described earlier.

67. A couple of comments suggested that FDA lacked the authority to establish the design control requirements.

FDA disagrees with the comments. The act and its legislative history make clear that FDA has the authority to impose those controls necessary to ensure that devices are safe and effective. The SMDA gave FDA explicit authority to promulgate design controls, including a process to assess the performance of a device (see section 520(f)(1)(A) of the act). The legislative history of the SMDA supports a ''*comprehensive* device design validation regulation.'' H. Rept. 808, 101st Cong., 2d sess. 23 (emphasis added). Congress stated that the amendment to the statute was necessary because almost half of all device recalls over a 5-year period were ''related to a problem with product design.'' Id. There is a thorough discussion on the evolution of and need for the design controls in the preamble to the November 23, 1993 (58 FR 61952), proposal.

68. A few comments objected to FDA requiring design controls for any class I devices in § 820.30(a).

FDA believes that, for the class I devices listed, design controls are necessary and has retained the requirements. Those relatively few devices, while class I, require close control of the design process to ensure that the devices perform as intended, given the serious consequences that could occur if their designs were flawed and the devices were to fail to meet their intended uses. In fact, some of the devices included on the list have experienced failures due to design related problems that have resulted in health hazards, injuries, or death. Further, verification, or even validation, cannot provide the assurance of proper design for some devices, especially those containing extensive software. Thus, all automated devices must be developed under the design control requirements.

69. Several comments stated that FDA has underestimated the complexity of a design project in requiring that the plans identify ''persons responsible for each activity'' in proposed § 820.30(b). One comment stated that ''define responsibility for implementation'' and ''activities shall be assigned'' were basically redundant requirements. A few other comments stated that ISO 9001:1994 does not call for the design plans to be ''approved'' and that this requirement should be deleted because it would be burdensome.

FDA agrees in part with the comments and has revised § 820.30(b) to require the plan to describe or reference design activities and define responsibility for implementing the activities, rather than requiring that the plan identify each person responsible for carrying out each activity. In making this change, FDA notes that § 820.20(b)(1) requires manufacturers to establish the appropriate responsibility for activities affecting quality, and emphasizes that the assignment of specific responsibility is important to the success of the design control program and to achieving compliance with the regulation. Also, the design and development activities should be assigned to qualified personnel equipped with adequate resources as required under § 820.20(b)(2). The requirements under § 820.30(b) were rewritten to be very similar to the requirements in ISO 9001:1994, sections 4.4.2 and 4.4.3. FDA does not agree that the design plan should not be ''approved.'' ISO 9001:1994, section 4.4.2 requires that the plan be ''updated,'' and section 4.4.3 requires that the plan be ''regularly reviewed.'' Therefore, the approval is consistent with ISO 9001:1994 and would not be unduly burdensome since the FDA does not dictate how or by whom the plan must be approved. The regulation gives the manufacturer the necessary flexibility to have the same person(s) who is responsible for the review also be responsible for the approval of the plan if appropriate.

70. A few comments stated that the proposed requirement to describe ''any interaction between or among different organizational and technical groups'' in § 820.30(b) for the design and development plan should be deleted because it is overly broad, unnecessary, and burdensome. One comment said that the communication expected between these groups should be clarified.

In response, FDA has amended the requirement as suggested by one comment so that the plan shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design process. Many organization functions, both inside and outside the design group, may contribute to the design process. For example, interfaces with marketing, purchasing, regulatory affairs, manufacturing, service groups, or information systems may be necessary during the design

development phase. To function effectively, the design plan must establish the roles of these groups in the design process and describe the information that should be received and transmitted.

71. One comment stated that the requirement in § 820.30(b) that manufacturers establish a design plan completely ignores the creative and dynamic process of designing by requiring a plan to have complete design and testing criteria established, with specifications, before the design process is started.

FDA disagrees with the comment. Section 820.30(b) does not require manufacturers to complete design and testing criteria before the design process begins. This section has been revised to state that ''plans shall be reviewed, updated, and approved as design and development evolves,'' indicating that changes to the design plan are expected. A design plan typically includes at least proposed quality practices, assessment methodology, recordkeeping and documentation requirements, and resources, as well as a sequence of events related to a particular design or design category. These may be modified and refined as the design evolves. However, the design process can become a lengthy and costly process if the design activity is not properly defined and planned. The more specifically the activities are defined up front, the less need there will be for changes as the design evolves.

72. One comment stated that the language contained in proposed § 820.30(c) should more closely match that of ISO 9001. Many other comments stated that the provision should not require the input requirements to ''completely'' address the intended use of the device because inputs could never ''completely'' address the intended use. Several comments stated that the requirement of ISO 9001 that ''incomplete, ambiguous or conflicting requirements shall be resolved with those responsible for imposing these requirements'' should be added to § 820.30(c), ''Design input,'' because it is important that the regulation identify the method of resolving conflicting information.

FDA agrees with the harmonization comment and has revised the language to incorporate the requirement of section 4.4.4, ''Design input,'' of ISO 9001:1994. FDA does not believe that it is necessary to have identical language to harmonize quality system requirements. ISO 9001:1994, section 4.4.1, ''General,'' requires that the manufacturer ''establish and maintain documented procedures to control and verify the design of the product in order to ensure that the specified requirements are met.'' FDA's regulation, under § 820.30(a), imposes the same requirements.

Regarding the comments that input requirements cannot completely address the intended use of the device, FDA recognizes that the provision could be interpreted to impose a burden that may not always be possible to meet and has deleted the word ''completely.'' FDA did not intend the provision to suggest that a manufacturer must foresee every possible event.

FDA emphasizes, however, that the section requires the manufacturer to ensure that the design input requirements are appropriate so the device will perform to meet its intended use and the needs of the user. In doing this, the manufacturer must define the performance characteristics, safety and reliability requirements, environmental requirements and limitations, physical characteristics, applicable standards and regulatory requirements, and labeling and packaging requirements, among other things, and refine the design requirements as verification and validation results are established. For example, when designing a device, the manufacturer should conduct appropriate human factors studies, analyses, and tests from the early stages of the design process until that point in development at which the interfaces with the medical professional and the patient are fixed. The human interface includes both the hardware and software characteristics that affect device use, and good design is crucial to logical, straightforward, and safe device operation. The human factors methods used (for instance, task/function analyses, user studies, prototype tests, mock-up reviews, etc.) should ensure that the characteristics of the user population and operating environment are considered. In addition, the compatibility of system components should be assessed. Finally, labeling (e.g., instructions for use) should be tested for usability.

FDA agrees with the comments, in that it is important that incomplete, ambiguous, or conflicting requirements be resolved with those responsible for imposing these requirements. Therefore, FDA has added the requirement that the procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. FDA notes that this must be done to ''ensure that the design requirements are appropriate and address the intended use of the device,'' as required under § 820.30(c).

73. A few other comments stated that ISO 9001:1994 does not call for the design input to be ''approved'' and therefore, this requirement should be deleted because it would be burdensome.

FDA does not agree that the ''approval'' of design input requirements should be deleted, nor that the requirement is inconsistent with ISO. ISO 9001:1994, section 4.4.4, ''Design Input,'' requires that the design input requirements be ''reviewed by the supplier for adequacy.'' Therefore, the approval would not add any additional burden because FDA does not dictate how or by whom the design input requirements must be approved, thus giving the manufacturer the necessary flexibility to have the same person(s) who is responsible for the ''review for adequacy'' also be responsible for the approval, if appropriate. Further, it is important that the design input be assessed as early as possible in the development process, making this an ideal time in the device's design development to have a design review to ''approve'' the design input.

74. A few comments stated that the proposed requirement under § 820.30(c) that ''design input shall be reviewed and approved by a designated qualified individual'' should be deleted as it implies that one person must be designated to review and approve a design, and that there may not be one person who is qualified to assess all of the design input requirements. Addressing the same point, several comments suggested that the provision be revised to allow for more than one person to review and approve the design. One comment said that the FDA's requirement appears to be at odds with the team approach.

FDA agrees with the concern expressed by the comments and has modified the requirement to allow more than one individual to review and approve the design input. FDA endorses the team approach and believes that designs should be reviewed and evaluated by all disciplines necessary to ensure the design input requirements are appropriate.

75. Two comments stated that proposed § 820.30(c) should be reworded to focus on systems for assuring adequate design input, not on the input itself. One additional comment on this section said that the design input requirements should include not only the device's intended use and needs of the user, but the environmental limits of where it will be used.

FDA agrees that procedures for ensuring appropriate design controls are of the utmost importance and has modified the section to clarify that the

manufacturer must establish and maintain procedures to ensure that the design requirements are properly addressed. FDA made this change to the other paragraphs as well, but notes that § 820.30(a), ''General,'' requires the manufacturer to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. The sections that follow set forth some of the requirements for which procedures must be established. It should be emphasized that the input itself must also be appropriate; the requirement is for the procedures to be defined, documented, *and implemented*. Thus, if the input requirements related to a device fail to address the intended use of the device, for example, the manufacturer has failed to comply with the provision.

FDA also agrees with the additional comment but believes that identifying and establishing the environmental limits for safe and effective device operation is inherent in the requirements for ensuring that a device is appropriate for its intended use. Some factors that must be considered when establishing inputs include, where applicable, a determination of energy (e.g., electrical, heat, and electromagnetic fields), biological effects (e.g., toxicity and biocompatibility) and environmental effects (e.g., electromagnetic interference and electrostatic discharge).

76. Several comments stated that proposed § 820.30(f), ''Design output,'' should be rewritten or deleted because many of the requirements were already stated in proposed §§ 820.30(d), ''Design verification,'' and 820.30(e), ''Design review,'' and, if retained, should be reordered similar to ISO 9001.

FDA agrees in part with the comments and has rewritten the requirements of design output to be consistent with ISO 9001:1994, section 4.4.5, ''Design output,'' and reordered the sections to be consistent with ISO 9001:1994. FDA retained the provision, however, because it does not agree that the section is redundant with the sections on design verification, design validation, or design review. Design output are the design specifications which should meet design input requirements, as confirmed during design verification and validation and ensured during design review. The output includes the device, its labeling and packaging, associated specifications and drawings, and production and quality assurance specifications and procedures. These documents are the basis for the DMR. The total finished design output consists of the device, its labeling and packaging, and the DMR.

77. One comment stated that the sentence ''Design output procedures shall ensure that design output meets the design input requirements'' is redundant with the requirement under design verification. Another comment asked what is meant by ''release.''

FDA agrees with the first comment and has deleted that sentence in § 820.30(d) but notes that the design output must be documented and expressed *in terms that can be verified* against the design input requirements.

Design output can be ''released'' or transferred to the next design phase at various stages in the design process, as defined in the design and development plan. The design output is reviewed and approved before release or transfer to the next design phase or production. The design output requirements are intended to apply to all such stages of the design process.

78. One small manufacturer commented that the problems that § 820.30(e), ''Design review,'' is meant to reveal involve coordination, cooperation, or communication difficulties among the members of an organization and that these difficulties do not exist in a small company. Therefore, the comment stated that the design review requirements should not apply to small manufacturers.

The purpose of conducting design reviews during the design phase is to ensure that the design satisfies the design input requirements for the intended use of the device and the needs of the user. Design review includes the review of design verification data to determine whether the design outputs meet functional and operational requirements, the design is compatible with components and other accessories, the safety requirements are achieved, the reliability and maintenance requirements are met, the labeling and other regulatory requirements are met, and the manufacturing, installation, and servicing requirements are compatible with the design specifications. Design reviews should be conducted at major decision points during the design phase.

For a large manufacturer, design review provides an opportunity for all those who may have an impact on the quality of the device to provide input, including manufacturing, quality assurance, purchasing, sales, and servicing divisions. While small manufacturers may not have the broad range of disciplines found in a large company, and the need to coordinate and control technical interfaces may be lessened, the principles of design review still apply. The requirements under § 820.30(e) allow small manufacturers to tailor a design review that is appropriate to their individual needs.

79. One comment stated that the wording of proposed § 820.30(e) implies that only one design review is expected, and that design review should be conducted at several stages of product development. Several comments stated that to demand that every design review be conducted by individuals who do not have direct responsibility for design development is impractical, especially for small companies.

FDA agrees with the first comment and has rewritten the requirement to make clear that design reviews must be conducted at appropriate stages of design development, which must be defined in the established design and development plan. The number of design reviews will depend on the plan and the complexity of the device. FDA also amended the requirements so that the results of a design review include identification of the design, the date, and the individual(s) performing the review. Thus, multiple reviews can occur and the manufacturer must document what is being reviewed, when, and by whom.

FDA never intended to mandate that an individual without design responsibility conduct the design reviews and, to clarify its position, has rewritten the requirement. The requirement now states that the procedures shall ensure that each design review includes an individual(s) who does not have direct responsibility for the design stage being reviewed. This requirement will provide an ''objective view'' from someone not working directly on that particular part of the design project, to ensure that the requirements are met. In making this change, FDA also notes that it was not FDA's intention to prohibit those directly responsible for the design from *participating* in the design review.

80. One comment stated that as part of the systematic review of the adequacy of the device design, it is occasionally necessary to produce a prototype device and have it evaluated by a physician who is an expert in the area of the device's intended use. Thus, the comment stated that the regulation should be revised to allow a means for a manufacturer to ship a prototype device to a physician for evaluation. One comment questioned whether design verification and validation can be conducted using prototypes or machine shop models.

FDA regulations do not prohibit the shipment of prototypes for clinical or

other studies. Prototypes used in clinical studies involving humans may be shipped in accordance with the IDE provisions in part 812 (21 CFR part 812).

FDA understands that it is not always practical to conduct clinical studies on finished production units and, therefore, the use of prototypes in clinical studies is acceptable. When prototype devices are used on humans they must be verified as safe to the maximum extent feasible. Final design validation, however, cannot be done on prototypes because the actual devices produced and distributed are seldom the same as the research and development prototypes. The final verification and validation, therefore, must include the testing of actual production devices under actual or simulated use conditions.

81. A few comments stated that § 820.30(d), ''Design verification,'' should be rewritten and reordered similar to ISO 9001.

FDA agrees with the comments and has rewritten and reordered this section to be consistent with ISO 9001:1994. The language in revised § 820.30(f) and (g) incorporates the requirement of ISO 9001:1994, sections 4.4.7, ''Design verification,'' and 4.4.8, ''Design validation,'' respectively.

Under the revised provisions, the design must be verified and validated. It is important to note that design validation follows successful design verification. Certain aspects of design validation can be accomplished during the design verification, but design verification is not a substitute for design validation. Design validation should be performed under defined operating conditions and on the initial production units, lots, or batches, or their equivalents to ensure proper overall design control and proper design transfer. When equivalent devices are used in the final design validation, the manufacturer must document in detail how the device was manufactured and how the manufacturing is similar to and possibly different from initial production. Where there are differences, the manufacturer must justify why design validation results are valid for the production units, lots, or batches. Manufacturers should not use prototypes developed in the laboratory or machine shop as test units to meet these requirements. Prototypes may differ from the finished production devices. During research and development, conditions for building prototypes are typically better controlled and personnel more knowledgeable about what needs to be done and how to do it than are regular production personnel. When going from laboratory to scale-up production, standards, methods, and procedures may not be properly transferred, or additional manufacturing processes may be added. Often, changes not reflected in the prototype are made in the device to facilitate the manufacturing process, and these may adversely affect device functioning and user interface characteristics. Proper testing of devices that are produced using the same methods and procedures as those to be used in routine production will prevent the distribution and subsequent recall of many unacceptable medical devices.

In addition, finished devices must be tested for performance under actual conditions of use or simulated use conditions in the actual or simulated environment in which the device is expected to be used. The simulated use testing provision no longer requires that the testing be performed on the *first three* production runs. However, samples must be taken from units, lots, or batches that were produced using the same specifications, production and quality system methods, procedures, and equipment that will be used for routine production. FDA considers this a critical element of the design validation. The requirement to conduct simulated use testing of finished devices is found in the original CGMP in § 820.160, as part of finished device inspection. This requirement has been moved to § 820.30(g) because FDA believes that simulated use testing at this point is more effective in ensuring that only safe and effective devices are produced. Manufacturers must also conduct such tests when they make changes in the device design or the manufacturing process that could affect safety or effectiveness as required in the original CGMP in § 820.100(a)(2). The extent of testing conducted should be governed by the risk(s) the device will present if it fails. FDA considers these activities essential for ensuring that the manufacturing process does not adversely affect the device.

Design validation may also be necessary in earlier stages, prior to product completion, and multiple validations may need to be performed if there are different intended uses. Proper design validation cannot occur without following all the requirements set forth in the design control section of the regulation.

82. Several comments stated that adequate controls for verification of design output are contained in proposed § 820.30(d), ''Design verification,'' and repeated in proposed § 820.30(f), ''Design output.'' One comment stated that this section will place undue burden on designers and require additional documentation which will add little value to a device's safety and effectiveness.

FDA disagrees with the comments. Revised § 820.30(f), ''Design verification,'' and § 820.30(g), ''Design validation,'' require verification and validation of the design output. Section 820.30(d), ''Design output,'' requires that the output be documented in a fashion that will allow for verification and validation. These sections thus contain different requirements that are basic to establishing that the design output meets the approved design requirements or inputs, including user needs and intended uses. All the requirements are essential to assuring the safety and effectiveness of devices. FDA does not believe that these requirements place undue burden on designers or require additional documentation with no value added. These basic requirements are necessary to assure the proper device performance, and, therefore, the production of safe and effective devices, and are acknowledged and accepted as such throughout the world.

83. Several comments stated that the term ''hazard analysis'' should be defined in reference to design verification. A couple of comments stated that the proposed requirement for design verification, to include software validation and hazard analysis, where applicable, was ambiguous, and may lead an FDA investigator to require software validation and hazard analysis for devices in cases where it is not needed. One comment stated that FDA should provide additional guidance regarding software validation and hazard analysis and what investigators will expect to see. Another comment stated that by explicitly mentioning only software validation and hazard analysis, FDA was missing the opportunity to introduce manufacturers to some powerful and beneficial tools for better device designs and problem avoidance.

FDA has deleted the term ''hazard analysis'' and replaced it with the term ''risk analysis.'' FDA's involvement with the ISO TC 210 made it clear that ''risk analysis'' is the comprehensive and appropriate term. When conducting a risk analysis, manufacturers are expected to identify possible hazards associated with the design in both normal and fault conditions. The risks associated with the hazards, including those resulting from user error, should then be calculated in both normal and fault conditions. If any risk is judged unacceptable, it should be reduced to acceptable levels by the appropriate

means, for example, by redesign or warnings. An important part of risk analysis is ensuring that changes made to eliminate or minimize hazards do not introduce new hazards. Tools for conducting such analyses include Failure Mode Effect Analysis and Fault Tree Analysis, among others.

FDA disagrees with the comments that state the requirement is ambiguous. Software must be validated when it is a part of the finished device. FDA believes that this control is always needed, given the unique nature of software, to assure that software will perform as intended and will not impede safe operation by the user. Risk analysis must be conducted for the majority of devices subject to design controls and is considered to be an essential requirement for medical devices under this regulation, as well as under ISO/CD 13485 and EN 46001. FDA has replaced the phrase ''where applicable'' with ''where appropriate'' for consistency with the rest of the regulation.

FDA believes that sufficient domestic and international guidelines are available to provide assistance to manufacturers for the validation of software and risk analysis. For example, ''Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review,'' August 1991; ''A Technical Report, Software Development Activities,'' July 1987; and ISO–9000–3 contain computer validation guidance. Further, FDA is preparing a new ''CDRH Guidance for the Scientific Review of Pre-Market Medical Device Software Submissions.'' Regarding guidance on ''risk analysis,'' manufacturers can reference the draft EN (prEN) 1441, ''Medical Devices—Risk Analysis'' standard and the work resulting from ISO TC 210 working group No. 4 to include ISO/CD 14971, ''Medical Devices—Risk Management—Application of Risk Analysis to Medical Devices.''

FDA disagrees that it is missing the opportunity to introduce manufacturers to some powerful and beneficial tools for better device designs and problem avoidance because the manufacturer must apply current methods and procedures that are appropriate for the device, to verify and validate the device design under the regulation. Therefore, FDA need not list all known methods for meeting the requirements. A tool that may be required to adequately verify and validate one design may be unnecessary to verify and validate another design.

84. One comment stated that for some design elements it may be more appropriate to reference data from another prior experimentation rather than conduct new testing, and that the requirement to list verification methods should be modified.

FDA agrees in part with the comment. The revised language of § 820.30(f) will permit the use of data from prior experimentation when applicable. When using data from previous experimentation, manufacturers must ensure that it is adequate for the current application.

85. ''Design transfer,'' now § 820.30(h), has been revised in response to the many comments objecting to the requirements in the proposed section on ''Design transfer.'' Specifically, the proposed requirement for testing production units under actual or simulated use conditions was rewritten and moved to current § 820.30(g), ''Design validation.''

FDA again emphasizes that testing production units under actual or simulated use conditions prior to distribution is crucial for ensuring that only safe and effective devices are distributed and FDA has therefore retained the requirement. ISO 9001:1994 discusses this concept in notes 12 and 13. As noted above, it is not always possible to determine the adequacy of the design by successfully building and testing prototypes or models produced in a laboratory setting.

The requirement for testing from the first three production lots or batches has been deleted. While FDA believes that three production runs during process validation (process validation may be initiated before or during design transfer) is the accepted standard, FDA recognizes that all processes may not be defined in terms of lots or batches. The number three is, however, currently considered to be the acceptable standard. Therefore, although the number requirement is deleted, FDA expects validation to be carried out properly in accordance with accepted standards, and will inspect for compliance accordingly.

Revised § 820.30(h) now contains a general requirement for the establishment of procedures to ensure that the design basis for the device is correctly translated into production methods and procedures. This is the same requirement that is contained in § 820.100(a) of the original CGMP regulation.

86. A few comments stated that the proposed requirements for ''Design release'' would prohibit the release of components, partial designs, and production methods before the design was final because the requirements mandate a review of all drawings, analysis, and production methods before allowing the product to go into production. Several comments stated that the proposed section on ''Design release'' was a duplication of requirements in other paragraphs of § 820.30 and should be deleted.

FDA did not intend the requirements for ''Design release'' to prohibit manufacturers from beginning the production process until all design activities were completed. The intent of the requirement was to ensure that all design specifications released to production have been approved, verified, and validated before they are implemented as part of the production process. This requirement is now explicitly contained in § 820.30(d).

FDA agrees in part with the second set of comments and has moved the requirement that design output be reviewed and approved to current § 820.30(d), ''Design output.'' The remainder of the requirements have been deleted.

87. Several comments on § 820.30(i), ''Design changes,'' stated that it is unnecessary to control all design changes and to do so would inhibit change and innovation.

FDA disagrees with the comments. Manufacturers are not expected to maintain records of all changes proposed during the very early stages of the design process. However, all design changes made after the design review that approves the initial design inputs for incorporation into the design, and those changes made to correct design deficiencies once the design has been released to production, must be documented. The records of these changes create a history of the evolution of the design, which can be invaluable for failure investigation and for facilitating the design of future similar products. Such records can prevent the repetition of errors and the development of unsafe or ineffective designs. The evaluation and documentation should be in direct proportion to the significance of the change. Procedures must ensure that after the design requirements are established and approved, changes to the design, both pre- production and post-production are also reviewed, validated (or verified where appropriate), and approved. Otherwise, a device may be rendered unable to properly perform, and unsafe and ineffective. ISO 9001:1994, section 4.4.9, similarly provides that ''all design changes and modifications shall be identified, documented, reviewed, and approved by authorized personnel before their implementation.''

Note that when a change is made to a specification, method, or procedure, each manufacturer should evaluate the

change in accordance with an established procedure to determine if the submission of a premarket notification (510(k)) under § 807.81(a)(3) (21 CFR 807.81(a)(3)), or the submission of a supplement to a PMA under § 814.39(a) (21 CFR 814.39) is required. Records of this evaluation and its results should be maintained.

88. Several comments recommended that only changes after design validation and design transfer to full-scale production need to be documented.

FDA disagrees with the comments. The safety and effectiveness of devices cannot be proven by final inspection or testing. Product development is inherently an evolutionary process. While change is a healthy and necessary part of product development, quality can be ensured only if change is controlled and documented in the development process, as well as the production process. Again, manufacturers are not expected to maintain records of changes made during the very early stages of product development; only those design changes made after the approval of the design inputs need be documented. Each manufacturer must establish criteria for evaluating changes to ensure that the changes are appropriate for its designs.

89. One comment on proposed § 820.30(i), ''Design changes,'' stated that validation of design changes is not always necessary and the regulation should provide for other methods to be used. FDA agrees with the comments and has amended the requirement to permit verification where appropriate. For example, a change in the sterilization process of a catheter will require validation of the new process, but the addition of more chromium to a stainless steel surgical instrument may only require verification through chemical analysis. Where a design change cannot be verified by subsequent inspection and test, it must be validated.

90. Many comments noted that the acronym for proposed design history record (DHR) was the same as that of ''device history record'' (DHR), and suggested that the name of the ''design history record'' be changed. Several comments stated that the requirements of the ''design history record'' should be deleted because they were redundant with the requirements of the ''device master record.''

FDA agrees with the first set of comments and has changed the name to ''design history file.''

FDA disagrees with the second set of comments. The DMR contains the documentation necessary to produce a device. The final design output from the design phase, which is maintained or referenced in the DHF, will form the basis or starting point for the DMR. Thus, those outputs must be referred to or placed in the DMR. The total finished design output includes the final device, its labeling and packaging, and the DMR that includes device specifications and drawings, as well as all instructions and procedures for production, installation, maintenance, and servicing. The DHF, in contrast, contains or references all the records necessary to establish compliance with the design plan and the regulation, including the design control procedures. The DHF illustrates the history of the design, and is necessary so that manufacturers can exercise control over and be accountable for the design process, thereby maximizing the probability that the finished design conforms to the design specifications.

91. A few comments stated that the proposed requirements in § 820.30(j) for the design history record should allow a single design history record for each device family or group having common design characteristics.

FDA agrees with the comments. The intent of the DHF is to document, or reference the documentation of, the activities carried out to meet the design plan and requirements of § 820.30. A DHF is, therefore, necessary for each type of device developed. The DHF must provide documentation showing the actions taken with regard to each type of device designed, not generically link devices together with different design characteristics and give a general overview of how the output was reached.

92. Some comments stated that the requirement that the DHF contain ''all'' records necessary to demonstrate that the requirements are met should be deleted because not ''all'' efforts need documentation.

FDA received similar comments on almost every section of the regulation that had the word ''all.'' The proposed requirement does not state that *all* records must be contained in the DHF, but that all records necessary to demonstrate that the requirements were met must be contained in the file. FDA has deleted the word ''all'' but cautions manufacturers that the complete history of the design process should be documented in the DHF. Such records are necessary to ensure that the final design conforms to the design specifications. Depending on the design, that may be relatively few records. Manufacturers who do not document all their efforts may lose the information and experience of those efforts, thereby possibly requiring activities to be duplicated.

D. Document Controls (Subpart D)

93. One comment stated that subpart D of part 820 should be titled ''Document Controls,'' instead of the proposed ''Document and Record Controls'' because the ''record'' requirements are addressed in subpart M. One comment stated that removal of obsolete or unneeded documents should be performed to maintain the integrity of the product configuration and the quality system. The comment suggested adding a requirement for a verification step for document distribution and removal to ensure this important element of a quality system is performed correctly. A few comments stated that proposed § 820.40 should be rewritten to be similar to ISO 9001 and to delete the requirement that documents be ''accurate'' because the comments feared that typographical errors would be considered violations.

FDA agrees with the first comment and has changed the title accordingly. FDA agrees in part with the second comment. The verification of document distribution and removal is very important and can directly affect the quality of a product. Section 820.40, which requires that the manufacturer establish and maintain procedures to control all documents, including those that are obsolete and/or to be removed, requires that the removal (or prevention of use) of obsolete documents be verified. FDA agrees in part with the last set of comments and has rewritten the section, following ISO 9001:1994, to be a general requirement for procedures to control documents that are required under the regulation. The procedures established must, among other things, ensure control of the accuracy and usage of current versions of the documents and the removal or prevention from use of obsolete documents, as well as ensure that the documentation developed is adequate to fulfill its intended purpose or requirement. FDA retained the requirement that the procedures ensure that documents meet the requirements of the regulation because that is the purpose of controlling the documents. FDA deleted the term ''accurate'' but notes that a typographical error can change the meaning of a document and have undesirable consequences.

94. Several comments on proposed § 820.40(a), ''Document approval and issue,'' as well as other sections throughout the regulation, suggested that the term ''signature'' be replaced by the term ''identification.'' Such a change would allow for electronic or computerized identification in lieu of formal written signatures. Other comments stated that ''or stamps''

should be added after ''signature'' since they are legally recognized in some foreign countries.

FDA is aware that many documentation systems are now maintained electronically, and is in the process of developing an agency-wide policy that will be implemented through rulemaking on the use of electronic signatures. The agency identified several important issues related to the use of such signatures, including how to ensure that the identification is in fact the user's ''signature.'' These issues are discussed in FDA's ANPRM on the use of electronic signatures, published in the Federal Register on July 21, 1992 (57 FR 32185), and the proposed regulation published in the Federal Register on August 31, 1994 (59 FR 45160). Therefore, FDA has not revised the regulation to use the term ''identification,'' but notes that the quality system regulation's use of the term ''signature'' will permit the use of whatever electronic means the agency determines is the equivalent of a handwritten signature. FDA recommends that manufacturers use the two Federal Register documents as guidance until the regulation is finalized. FDA has not added the term ''or stamps'' to the regulation; however, stamps could be acceptable if the manufacturer has a formal procedure on how stamps are used in place of handwritten signatures. The procedure would have to address many of the same issues addressed in the electronic signature Federal Register documents, most importantly how the stamps would be controlled and how the manufacturer would ensure that the stamp was in fact the user's ''signature.''

95. Several comments stated that proposed § 820.40(b), ''Document distribution,'' should be rewritten to be consistent with ISO 9001.

In response, FDA has deleted the section. The requirements for making documents available at all appropriate locations (ISO 9001:1994, section 4.5.2(a)) and the requirements for promptly removing obsolete documents (ISO 9001:1994, section 4.5.2(b)) have been moved, in revised form, to § 820.40(a). In response to comments, FDA has added that obsolete documents, in lieu of being promptly removed from points of use, may be ''otherwise prevented from unintended use.''

96. Several comments suggested major changes to proposed § 820.40(c), ''Documentation changes.'' Some stated that the requirements should be revised to be consistent with ISO 9001. Others stated that the requirements related to validation should be rewritten and moved to another section under this part, because § 820.40(c) should only address document changes, not device changes. Several comments stated that the reference to determining whether a 510(k) or PMA supplement is required after making changes to a device should be deleted because it is covered under different parts of the act and regulations. One comment stated that the requirement in § 820.40(c) for changes to be ''approved by individuals in the same functions/organizations that performed the original review and approval, unless specifically designated otherwise'' is unrealistic and does not reflect the way things are done in real life.

FDA agrees with many of the comments and has substantially rewritten § 820.40(c), now designated as § 820.40(b), to relate specifically to changes to a document. The requirements are now very similar to the ISO 9001:1994 requirements in section 4.5.3. FDA has retained the requirement that the approved changes must be communicated in a timely manner to appropriate personnel. FDA has had many experiences where manufacturers made corrections to documents, but the changes were not communicated in a timely manner to the personnel utilizing the documents. The result of these untimely communications was the production of defective devices.

In addition, FDA has moved the requirement for validating production and process changes to § 820.70(b), ''Production and process changes,'' and notes that changes to the design specifications, at any time during the lifetime of the design of the device, must conform to the requirements in § 820.30(i), ''Design changes.''

FDA has also deleted the sentence referencing 510(k)'s and PMA supplements because FDA believes this is covered elsewhere, but notes that this sentence is in the preamble above for § 820.30(i).

FDA disagrees that the requirement for changes to be ''approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise'' should be deleted and notes that this is a requirement of ISO 9001:1994 as well. The intent of the requirement is to ensure that those who originally approved the document have an opportunity to review any changes because these individuals typically have the best insight on the impact of the changes. The requirement is flexible, however, because it permits the manufacturer to specifically designate individuals who did not perform the original review and approval to review and approve the changes. To designate such individuals, the manufacturer will need to determine who would be best suited to perform the function, thus ensuring adequate control over the changes. In this way, review and approval will not be haphazard.

97. One comment on proposed § 820.40(d), ''Documentation change record,'' stated that this section should be deleted because the other paragraphs of § 820.40 adequately cover the proposed requirements. Two comments suggested replacing the section with the requirements of section 4.5.2 of ISO 9001.

FDA has deleted § 820.40(d) and placed the revised requirements in paragraphs (a) and (b) of this section. The general requirement of § 820.40 now requires the manufacturer to establish adequate procedures to control all documents required by part 820. The procedures must cover the requirements listed in § 820.40 (a) and (b). Thus, the manufacturer must establish a procedure for ensuring that only the current and approved version of a document is used, achieving the objective of the ''Master list or equivalent document control procedure,'' required in ISO 9001:1994, section 4.5.2.

The other requirement in § 820.40(d), ''Document change record,'' was to maintain a record of changes, to include a description of the changes, among other things. FDA has retained this requirement and has moved it into § 820.40(b), ''Document changes,'' because the agency believes this information to be important and useful when investigating and performing corrective or preventive actions.

FDA believes § 820.40 on *Document controls* now adequately harmonizes with ISO 9001:1994, sections 4.5.1, 4.5.2, and 4.5.3.

E. Purchasing Controls (Subpart E)

98. One comment stated that the proposed CGMP regulation omits any discussion of contract reviews, such as that contained in ISO 9001, section 4.3. Rather than leaving these procedures to the interpretations of individual manufacturers and investigators, the comment stated that FDA should explicitly state its general policy regarding contract reviews in the regulation.

FDA agrees with the concepts underlying the contract review requirements of ISO 9001:1994, but believes these principles are already reflected in requirements in the regulation, such as §§ 820.50 *Purchasing controls* and 820.160 *Distribution*.

Therefore, the agency has not added a separate section on contract review.

99. One comment stated that the requirements in § 820.50 amount to overregulation. The comment stated that components are purchased by providing a specification sheet. They are then inspected upon receipt, and defective components are returned. According to the comment, under § 820.50, the manufacturer would be required to spend more time on paperwork, and product would still have to be inspected upon receipt. Another comment stated that the cost of the quality assurance documentation program is going to be significantly higher for a company that runs a Just In Time (JIT) program than what FDA estimated.

FDA disagrees with the comments. The failure to implement adequate purchasing controls has resulted in a significant number of recalls due to component failures. Most of these were due to unacceptable components provided by suppliers. Since FDA is not regulating component suppliers, FDA believes that the explicit addition to CGMP requirements of the purchasing controls of ISO 9001:1994 is necessary to provide the additional assurance that only acceptable components are used. To ensure purchased or otherwise received product or services conform to specifications, purchasing must be carried out under adequate controls, including the assessment and selection of suppliers, contractors, and consultants, the clear and unambiguous specification of requirements, and the performance of suitable acceptance activities. Each manufacturer must establish an appropriate mix of assessment and receiving acceptance to ensure products and services are acceptable for their intended uses. The specifications for the finished device cannot be met unless the individual parts of the finished device meet specifications. The most efficient and least costly approach is to ensure that only acceptable products and services are received. This means that only suppliers, contractors, and consultants that meet specifications should be used.

The regulation has been written to allow more flexibility in the way manufacturers may ensure the acceptability of products and services. Under the requirements, manufacturers must clearly define in the procedures the type and extent of control they intend to apply to products and services. Thus, a finished device manufacturer may choose to provide greater in-house controls to ensure that products and services meet requirements, or may require the supplier to adopt measures necessary to ensure acceptability, as appropriate. FDA generally believes that an appropriate mix of supplier and manufacturer quality controls are necessary. However, finished device manufacturers who conduct product quality control solely in-house must also assess the capability of suppliers to provide acceptable product. Where audits are not practical, this may be done through, among other means, reviewing historical data, monitoring and trending, and inspection and testing.

After evaluation of all of the comments on § 820.50, FDA has decided to change the wording of § 820.50(a) and adopt the wording of ISO 9001:1994 to make clear that manufacturers have flexibility in determining the degree of assessment and evaluation necessary for suppliers, contractors, and consultants. Thus the degree of supplier control necessary to establish compliance may vary with the type and significance of the product or service purchased and the impact of that product or service on the quality of the finished device. In addition, the requirement for manufacturers to establish assessment criteria has been deleted but the evaluation still must include a description how the assessment was made (according to what criteria or objective procedure) and the results must be documented. Each manufacturer must now define the type and extent of control it will exercise over suppliers, contractors, and consultants. This is consistent with the 1994 version of ISO 9001.

Thus, FDA believes that the flexibility of the regulation will allow manufacturers to implement JIT procedures without additional cost. In fact, the new regulation is more conducive to JIT practices by permitting the assessment or evaluation of product or services up front, thereby lessening the degree of in-house control that may be necessary.

100. Several comments said that it was unclear what FDA meant by the phrase ''or held by other persons under contract conform to specifications'' and that this phrase should be deleted.

FDA agrees with the comments and has deleted the phrase. The phrase was intended to mean product and services which were purchased or processed in some manner by other organizations. Section 820.50 now applies to ''purchased or otherwise received product and services'' to convey this meaning. FDA emphasizes that the requirements apply to all product and service received from outside of the finished device manufacturer, whether payment occurs or not. Thus, a manufacturer must comply with these provisions when it receives product or services from its ''sister facility'' or some other corporate or financial affiliate. ''Otherwise received product'' would include ''customer supplied product'' as in ISO 9001:1994, section 4.7, but would not apply to ''returned product'' from the customer.

101. One comment stated that ''manufacturing materials'' should be deleted from the first sentence of the introductory text of the proposed § 820.50, as the assessment of the manufacturers of manufacturing materials would be a monumental task.

FDA disagrees with the comment. The first sentence of the introductory text of § 820.50 is rewritten to be a general requirement that each manufacturer must establish procedures to ensure that received product and services (purchased or otherwise received) conform to specified requirements. All manufacturers are expected to apply controls to manufacturing materials appropriate to the manufacturing material, the intended use, and the effect of the manufacturing materials on safety and effectiveness. For example, the procedures necessary to ensure that a mold release agent conforms to specified requirements may be less involved than the procedures for controlling latex proteins. The provision allows the manufacturer the flexibility of establishing the procedures to meet its needs and to ensure that the product conforms to specified requirements.

102. One comment said that FDA should delete the last sentence of the introductory text of proposed § 820.50 because it is unnecessary for manufacturers to develop specifications for services that are unrelated to product or process quality, and because the terms ''service'' and ''other persons'' lack definition. Other comments stated that ''all'' should be deleted in the general requirement.

FDA disagrees with the comments. First, as used in the regulation, ''service'' means parts of the manufacturing or quality system that are contracted to others, for example, plating of metals, testing, and sterilizing, among others. Second, FDA believes that all suppliers of such services must be assessed and evaluated, just like a supplier of a product. As always, the degree of control necessary is related to the product or service purchased. FDA has, however, deleted the term ''provided by other persons'' because it was unnecessary. FDA did not delete the word ''all'' because, as discussed above, component manufacturers are not subject to this regulation, so it is the

finished device manufacturer who is responsible for ''all'' product and services.

103. One comment stated that many suppliers of components to the medical device industry have their quality systems certified to an ISO 9000 standard by an independent third party auditor, and that such registration of component manufacturers should be considered in vendor assessment plans.

FDA agrees in part with the comment in that certification may play a role in evaluating suppliers, but cautions manufacturers against relying solely on certification by third parties as evidence that suppliers have the capability to provide quality products or services. FDA has found during inspections that some manufacturers who have been certified to the ISO standards have not had acceptable problem identification and corrective action programs. Therefore, the initial assessment or evaluation, depending on the type and potential effect on device quality of the product or service, should be a combination of assessment methods, to possibly include third party or product certification. However, third party certification should not be relied on exclusively in initially evaluating a supplier. If a device manufacturer has established confidence in the supplier's ability to provide acceptable products or services, certification with test data may be acceptable.

104. Some comments stated that consultants should not be included in the regulation at all. Others stated that it was not consistent with ISO 9001.

FDA added ''consultants'' to § 820.50(a) in response to the comments from § 820.25(c). FDA disagrees that ''consultants'' should be deleted because over the years FDA has observed that a surprising number of firms hire consultants who have no particular expertise in the area in which the firm is seeking assistance. Section 820.50 addresses this problem by ensuring that a consultant's capability for the specific tasks for which he or she is retained be assessed and documented. Further, FDA does not believe this requirement is inconsistent with ISO 9001:1994 because ISO uses the term ''subcontractor.'' The term ''subcontractor'' includes consultants.

105. One comment said that requiring evaluation of potential suppliers, contractors, and consultants ''on the basis of their ability to meet requirements'' is vague and should be clearly defined.

FDA disagrees that the phrase is vague. Suppliers, contractors, and consultants selected by manufacturers of medical devices should have a demonstrated capability of providing products and services that meet the requirements established by the finished device manufacturer. The capability of the product or service suppliers should be reviewed at intervals consistent with the significance of the product or service provided and the review should demonstrate conformance to specified requirements.

106. One comment questioned the usefulness of § 820.50, given that the requirements under § 820.80 *Receiving, in-process, and finished device acceptance,* require manufacturers to establish and maintain procedures for acceptance of incoming components.

The intent of § 820.50 is to ensure that device manufacturers select only those suppliers, contractors, and consultants who have the capability to provide quality product and services. As with finished devices, quality cannot be inspected or tested into products or services. Rather, the quality of a product or service is established during the design of that product or service, and achieved through proper control of the manufacture of that product or the performance of that service. Section 820.50 thus mandates that products be manufactured and services be performed under appropriate quality assurance procedures. Finished device manufacturers are required under § 820.50 to establish the requirements for, and document the capability of, suppliers, contractors, and consultants to provide quality products and services.

Section 820.80 is specific to a device manufacturer's acceptance program. While finished device manufacturers are required to assess the capability of suppliers, contractors, and consultants to provide quality products and services, inspections and tests, and other verification tools, are also an important part of ensuring that components and finished devices conform to approved specifications. The extent of incoming acceptance activities can be based, in part, on the degree to which the supplier has demonstrated a capability to provide quality products or services. An appropriate product and services quality assurance program includes a combination of assessment techniques, including inspection and test.

107. Several comments stated that it was not clear how a manufacturer could evaluate an off-the-shelf component that is purchased from a distributor rather than directly from its manufacturer, and stated that it would not be helpful to audit the distributor.

FDA agrees that auditing a distributor would not meet the intent of § 820.50. Manufacturers should remember that the purpose of assessing the capability of suppliers is to provide quality products and to provide a greater degree of assurance, beyond that provided by receiving inspection and test, that the products received meet the finished device manufacturer's requirements. The agency recognizes that finished device manufacturers may not always be able to audit the supplier of a product. In such cases, the manufacturer must apply other effective means to assure that products are acceptable for use.

108. Many comments from both domestic and foreign firms in response to proposed § 820.22(b) said that making supplier audit reports subject to FDA review would have a major adverse impact on the relationships between the finished device manufacturers and their suppliers and service providers. Some stated that the requirement would cause suppliers to refuse to sell components to medical device manufacturers, especially suppliers who provide only a small part of their production to device manufacturers. Others said that this policy is not consistent with FDA's policy for internal audits.

FDA recognizes that quality audits of suppliers have a significant and demonstrated value as a management tool for corrective action, quality improvement, and overall assurance of component and service quality, and does not seek to undermine their value. Therefore, based on the concerns raised by the comments, FDA will not review supplier audit reports during a routine FDA inspection for compliance with part 820, as noted in § 820.180(c), ''Exceptions.'' The audit procedures, the evaluation procedures, and documents other than the supplier audit reports themselves that demonstrate conformance with § 820.50 will be subject to review by an FDA investigator.

109. One comment stated that it was unclear what is meant by the requirement to specify ''quality requirements'' that must be met by suppliers, contractors, and consultants, as stated in § 820.50(a).

The term ''quality requirements'' means the quality control and quality assurance procedures, standards, and other requirements necessary to assure that the product or service is adequate for its intended use. FDA does not believe the term is unclear.

110. Several comments on proposed § 820.50(b), ''Purchasing forms,'' suggested that the term ''forms'' be replaced by ''data.'' Other comments stated that use of the term would not allow electronic data exchange. One comment stated that the use of an

exclusive form for purchasing is unnecessary and redundant, and that it is unduly burdensome to require detailed documentation on those commonly available items such as fasteners. The comment stated that it is common practice to use prints or drawings to fulfill the purpose of the form.

FDA agrees in part with the comments, but does not believe that § 820.50(b) prohibits the use of drawings or prints, assuming that the documents contain data clearly describing the product or service ordered, and that the specified requirements are met. However, § 820.50(b) has been rewritten and now requires manufacturers to establish purchasing ''data.'' This provides manufacturers with the flexibility to use both written and electronic means to establish purchasing information.

111. One comment stated that the inclusion of an additional provision mandating that suppliers notify manufacturers of any change in their product or service places an undue burden on suppliers and inhibits their ability to make minor adjustments within the parameters of agreed upon specifications and quality requirements. Many other comments stated that the requirement in § 820.50(b) is feasible only for components that are custom made for the manufacturer, and is meaningless for off-the-shelf components purchased from distributors. Other comments stated that the requirement is part of the original CGMP regulation and experience has shown that suppliers are not willing to supply device manufacturers with such information. A few other comments stated that ''any'' should be deleted because the term is too broad and could result in burdensome reporting of variables which are irrelevant to the continued performance or specifications of the product or service.

FDA agrees in part with the comments and has amended the requirement to state that such agreement should be obtained ''where possible.'' FDA still believes that this change information is very important to the manufacturer, and that the manufacturer should obtain information on changes to the product or service. Where a supplier refuses to agree to provide such notification, depending on the product or service being purchased, it may render him an unacceptable supplier. However, where the product is in short supply and must be purchased, the manufacturer will need to heighten control in other ways.

FDA has also deleted the term ''any'' to give manufacturers the flexibility to define in the agreement the types of changes that would require notification.

112. One comment stated that § 820.50(b) should incorporate a provision that would allow manufacturers to cite published standards in purchasing forms as one suitable method for specifying purchased item quality requirements.

FDA believes the addition is unnecessary, because the regulation permits manufacturers to clearly describe or reference requirements. A reference could be to a standard.

113. One comment stated that it is unclear whether the requirement for a signature to approve purchasing documents pertains to approval of the form used for purchasing or approval of the individual purchasing transaction. The comment also stated that a signature approval by transaction is not practical for firms using electronic document transmittals.

FDA has rewritten the requirement to be more clear. The requirement is for approval of purchasing data or information on the purchasing document used to purchase a product or service. Thus, each manufacturer must review and approve the purchasing data before release of the data. Approval of each purchasing transaction is not required. FDA addressed the use of electronic signatures in response to another comment, and notes that FDA is in the process of developing an agency-wide policy on the use of electronic signatures.

114. One comment stated that purchasing is carried out verbally in many small firms, without the use of component-specific purchasing forms, and that the regulation should be revised to allow such verbal purchasing to continue.

FDA disagrees with the comment. About 15 percent of the recalls each year are due to unacceptable purchased products. Many of these products are unacceptable because the finished device manufacturer did not properly describe the product. The requirements for purchased products and services must be documented to ensure that the supplier, contractor, and consultant provide a product or service which conforms to specified requirements. This requirement, and the goal it seeks to achieve, are applicable to both small and large companies.

115. One comment stated that the requirement that purchasing forms spell out the specifications for manufacturing materials in all cases is excessive, and that the need for specifications should be based on the criticality of and risk associated with the use of the specific manufacturing material.

FDA agrees that the specifications for many manufacturing materials may be so well established that the trade name of the product may be sufficient to describe the material needed. For other materials, specific written specifications may be necessary to ensure that the desired materials are received. The extent of the specification detail necessary to ensure that the product or service purchased meets requirements will be related to the nature of the product or service purchased, taking into account the effect the product or service may have on the safety or effectiveness of the finished device, among other factors. The term ''specification'' has been replaced with the term ''specified requirements'' to better reflect the intent of the requirement.

116. FDA has deleted the last two sentences of § 820.50(b) in the Working Draft and has replaced them with a reference to § 820.40, the general document control provision. This does not change the requirement but simply eliminates any confusion about the reviews and approvals being duplicative.

F. Identification and Traceability (Subpart F)

i. Identification (§ 820.60)

117. A few comments on proposed §§ 820.60 *Identification and traceability* and 820.65 *Critical device, traceability* stated that the two sections should be rewritten to delete the distinction between critical and noncritical devices. Some stated they should be consistent with ISO.

FDA agrees in part with the comments and has rewritten § 820.60 to be consistent with ISO 9001:1994 and broad enough to allow the manufacturer the flexibility needed to identify product by whatever means described by the required procedure. The term ''critical device'' has also been deleted, and traceability is addressed solely in § 820.65.

118. One comment stated that manufacturing materials should be deleted from § 820.60, as the requirements are excessive and not economically justifiable with regard to such materials.

FDA disagrees with the comment. The purpose of § 820.60 is to ensure that all products, including manufacturing materials used in the manufacture of a finished device, are properly identified. This requirement is intended to help prevent inadvertent use or release of unacceptable product into manufacturing. It is as important that the proper manufacturing materials be

used as it is that the proper component be used.

119. A few comments thought that § 820.60 *Identification* in the Working Draft was redundant with § 820.86 *Acceptance status.*

FDA disagrees with the comments. Section 820.60 only requires that product be identified but says nothing about the acceptance status of that product. Section 820.86 requires that the acceptance status be identified so that inadvertent use of product does not occur. The manufacturer may choose to set up a system by which the identification required by § 820.60 can also show the acceptance status required by § 820.86, but this is up to the manufacturer.

ii. Traceability (§ 820.65)

120. A few comments stated that proposed § 820.65 *Critical devices, traceability* implies that traceability requirements exist for all devices. Several other written comments and oral testimony at the August and September 1995 meetings stated that the wording of the Working Draft was too broad, vague, and ambiguous, and in effect would require that all devices be traced.

As noted above, FDA has deleted the critical device terminology. Section 820.65 is now entitled *Traceability* and uses the definition from the original CGMP of a critical device to provide the necessary clarity and delineation for this requirement. Thus, traceability is required for the critical devices listed in the Federal Register notice of March 17, 1988 (53 FR 8854). However, FDA is using the definition of critical device in the requirement of § 820.65, rather than a reference to the 1988 list of critical devices, because that list has not been updated since 1988 and there are no plans to revise that list. Therefore, it is imperative that manufacturers use the definition within the requirement of § 820.65 to determine if a particular device needs to be traced; it may not be sufficient to rely solely on the 1988 list. Manufacturers may find it advantageous to provide unit, lot, or batch traceability for devices for which traceability is not a requirement to facilitate control and limit the number of devices that may need to be recalled due to defects or violations of the act.

It is important that the traceability requirements in part 820 are not confused with the Medical Device Tracking regulation in part 821 (21 CFR part 821). The *tracking regulation* is intended to ensure that tracked devices can be traced from the device manufacturing facility to the person for whom the device is indicated, that is, the patient. Effective tracking of devices from the manufacturing facility, through the distribution network (including distributors, retailers, rental firms and other commercial enterprises, device user facilities, and licensed practitioners) and, ultimately, to any person for whom the device is intended is necessary for the effectiveness of remedies prescribed by the act, such as patient notification (section 518(a) of the act (21 U.S.C. 360h(a)) or device recall (section 518(e).) In contrast, the *traceability provision* requires that a device that meets the definition of a ''critical device'' can be traced from the manufacturing facility only to the ''initial consignee'' as discussed in § 820.160 *Distribution.*

121. Another comment on proposed § 820.65 stated that critical device component traceability could be interpreted to be required for almost all electronic components and other components in a critical device. The comment stated that the extent of component traceability should be left to the manufacturer's discretion, since it is an economic risk decision. Several comments stated that component traceability should only be required ''where appropriate,'' that all ''critical device'' components do not require traceability to comply with the act.

FDA disagrees that the traceability determination should be based solely on economic risk. As noted in the preamble to the November 23, 1993, proposal (58 FR 61964), where traceability is important to prevent the distribution of devices that could seriously injure the user, traceability of components must be maintained so that potential and actual problem components can be traced back to the supplier. The revised requirement mandates traceability of components ''where appropriate'' as recommended by the GMP Advisory Committee and limited by the discussion in the scope, § 820.1(a)(3). The critical component definition in the original CGMP regulation may be used as guidance. However, to carry out the requirement of the revised provision, the manufacturer should perform risk analysis first on the finished device, and subsequently on the components of such device, to determine the need for traceability. FDA believes that the extent of traceability for both active and inactive implantable devices should include *all* components and materials used when such products could cause the medical device not to satisfy its specified requirements. ISO/CD 13485 also requires that the manufacturer's agents or distributors maintain records of distribution of medical devices with regard to traceability and that such records be available for inspection. This requirement is found in § 820.160 *Distribution* of this regulation and is consistent with the requirements in § 820.151 of the original CGMP.

While FDA understands that traceability entails additional cost, the agency notes that, if a product recall is necessary, more devices would be subject to recall if units, lots, or batches of specific devices are not traceable, with associated higher recall costs to the manufacturer.

G. Production and Process Controls (Subpart G)

i. Production and Process Controls (§ 820.70)

122. A few comments stated that the requirements in proposed § 820.70(a) *General* are similar to those in ISO 9001, but that ISO 9001 makes clear that the requirements apply only ''where applicable'' and where deviations from device specifications would ''directly affect quality.'' The comments suggested that FDA similarly employ such language to avoid being too restrictive and overly burdensome.

The requirements in § 820.70(a) are intended to ensure that each manufacturer produces devices that conform to their specifications. Thus, where any deviations from specifications could occur during manufacturing, the process control procedures must describe those controls necessary to ensure conformance. Those controls listed in the regulation may not always be relevant; similarly others may be necessary. For example, where deviations from device specifications could occur as a result of the absence of written production methods, procedures, and workmanship criteria, such production controls are required. Thus, FDA has retained the provision, but revised it slightly to conform with the original CGMP requirements in § 820.100(b)(1).

As noted, the process control requirements apply when any deviation from specifications could occur. FDA believes that such deviations must be controlled, and that linking the requirements to deviations that directly affect quality is inappropriate and subjective, and that it could lead to the manufacture of potentially dangerous devices through the lack of control of processes known to directly affect a device's specifications. Therefore, the provision has not been restricted in this manner. FDA has, however, revised the requirements to state ''Where process controls are needed they shall include:'' to make it clear that a manufacturer only has to comply with the requirements

stated in § 820.70 (a)(1) through (a)(5) if the general criteria described in § 820.70(a) have been met.

123. One comment stated that the second sentence of proposed § 820.70(a) was too restrictive, in that some processes can be accomplished by adequately trained personnel without the use of procedures.

FDA disagrees with the comment because the establishment of procedures is necessary to ensure consistency in manufacture. The procedures may be tailored under the requirement to cover only those controls necessary to ensure that a device meets its specifications. FDA notes that the deletion of the word ''all'' does not alter the requirements. The first sentence in the general requirement also serves to tie the production and process controls to the design and development phase where many of these controls are originally established in order for the device to conform to its design specifications.

In addition to these changes, FDA has added the requirement that production processes be ''monitored'' because a manufacturer must monitor a controlled process to ensure that the process remains in control.

124. FDA deleted the requirement for process controls related to ''installation and servicing'' from proposed § 820.70 (a)(1) and (a)(2) in response to comments. Such control is adequately assured by the requirements in §§ 820.170 *Installation* and 820.200 *Servicing.* FDA amended § 820.70(a)(3) in response to some comments that were confused about compliance with ''applied reference standards.'' The term ''applied'' was replaced with ''specified'' to make it clear that the manufacturer must comply with reference standards or codes which he or she has specified in the DMR. FDA has also deleted ''and process control procedures'' because that requirement is inherent in § 820.70(a), ''General.'' FDA amended § 820.70(a)(5) by adding ''identified and approved'' in response to comments and to clarify that the ''representative samples'' have to be identified and deemed appropriate before they are used as reference standards.

125. One comment believed that there is no longer a requirement that process changes be validated. Other comments on the Working Draft § 820.70(b) stated the requirement was still confusing with respect to ''unless inspection and test fully verifies,'' and when the ''approval'' was to occur.

Revised § 820.70(b), ''Production and process changes,'' addresses the requirement for production and process changes to be ''verified or where appropriate validated according to § 820.75.'' This requirement for validation was moved from § 820.40(c), in revised form, to § 820.70. Verification was added to give the manufacturer the flexibility to verify changes that can be tested and inspected because FDA believes that validation is not always necessary. FDA has provided guidance on when changes should be validated in its ''Guideline on General Principles of Process Validation.'' The agency notes that wherever changes may influence a validated process, the process must be revalidated as described in § 820.75. A few examples of processes that must be validated include sterilization, molding, and welding.

FDA has deleted the last part in § 820.70(b) of the Working Draft about approving changes and has replaced it with ''Changes shall be approved in accordance with § 820.40.'' This does not change the requirement but simply refers back to § 820.40 because this requires the same review and approval. This was done to eliminate any confusion about the reviews and approvals being duplicative.

126. The EU Commission and others stated that environmental conditions only affect the quality of certain devices and that the requirements should, therefore, be limited in their application. Other comments stated that the requirements in proposed § 820.70(b), ''Environmental control,'' were not consistent with the requirements in the original CGMP, § 820.46. Another comment requested that FDA delete the reference to ''facilities'' inspection and limit the requirement to review of the control system, as contained in the original CGMP regulation.

FDA has amended the requirements now in § 820.70(c) to apply only where environmental conditions could ''reasonably be expected to have an adverse effect on product quality.'' The requirements for procedures to ensure control of conditions, periodic inspection of control systems, and documentation and review of results are similar to the original CGMP requirements. However, the specific list of conditions to be considered for control, which was carried over from the original CGMP regulation to the proposal, was deleted in response to a comment from the GHTF that the list would be better suited for a guidance document. FDA agrees that it is not necessary to give examples of conditions that may need controlling in a regulation, and notes that lighting, ventilation, temperature, humidity, air pressure, filtration, airborne contamination, and static electricity are among many conditions that should be considered for control.

FDA reworded the requirement to make it clear that the inspection must be of the control system. FDA also added that the inspection of the control system(s) shall include ''any necessary equipment,'' e.g., pumps, filters, measurement equipment, etc. The sufficiency of facilities is covered in a new § 820.70(f), ''Buildings,'' that requires that buildings be of suitable design and contain sufficient space to allow for the proper manufacture of devices. Section 820.70(f) is worded similarly to the original CGMP regulation § 820.40, and is intended to achieve the same objectives as that section.

127. One comment stated that the last sentence of proposed § 820.70(b), ''Environmental control,'' should be deleted because it is redundant with the audits required in § 820.22(a). Another comment said that environmental conditions are currently reviewed via internal audit, which an FDA investigator cannot review.

FDA disagrees with the comments. The inspection and review of environmental control systems are routine quality assurance functions that are part of the production quality assurance program. The audits required by § 820.22(a) are audits of the quality system, conducted to ensure the adequacy of and conformance with the quality system requirements. The requirement to conduct a quality audit is in addition to other provisions in the regulation which require that a manufacturer review its specific controls to ensure the requirements are met. FDA may review the activities and results of environmental control system inspections.

128. The GHTF commented that the requirements of proposed § 820.70(c), ''Cleaning and sanitation,'' should be placed in guidance.

After careful consideration, FDA agrees that a separate section on cleaning and sanitation is unnecessary. The objective of proposed § 820.70(c) is adequately met through the requirement of § 820.70(e), ''Contamination control,'' and § 820.70(a), the general process control procedure requirement. Contamination control must include establishing and maintaining adequate cleaning procedures and schedules, if such control is necessary to meet manufacturing process specifications. In addition, § 820.25 *Personnel* requires that employees have a thorough understanding of their job functions, which would include a requirement that the appropriate employees comprehend

the cleanliness and sanitation procedures.

129. The GHTF and others commented that the requirements of proposed § 820.70 (d)(1) through (d)(3) should be deleted and placed in guidance because they are redundant with the first sentence in proposed § 820.70(d), ''Personnel health and cleanliness.''

FDA agrees with the comments and has deleted § 820.70 (d)(1) through (d)(3). FDA has also rewritten the section, now entitled ''Personnel,'' to require procedures to achieve the desired result, rather than dictate the means to achieve the result. The section as rewritten provides the manufacturer with more flexibility and is consistent with ISO/CD 13485. Under this section, a manufacturer's requirements must not permit unclean or inappropriately clothed employees, or employees with medical conditions, to work with devices where such conditions could reasonably be expected to have an adverse effect on product quality. The procedures must also address acceptable clothing, hygiene, and personal practices, if contact between personnel and product or environment could reasonably be expected to have an adverse effect on product quality.

FDA also added the requirement, from ISO/CD 13485, that personnel who are working temporarily (such as maintenance and cleaning personnel) under special environmental conditions (such as a clean room) be appropriately trained or supervised by someone trained to work in such an environment.

130. One comment stated that the requirements of § 820.70(e), ''Contamination control,'' should be deleted and placed in guidance. Another comment stated that the reference to manufacturing materials should be deleted because it is redundant with § 820.70(g), ''Equipment.''

FDA has rewritten the section to delete the specific references to contaminants that probably gave rise to the suggestion that the section would be more appropriate as guidance. The section now contains a broad requirement for the establishment of procedures to prevent contamination of equipment or product by any substance that could reasonably be expected to have an adverse effect on product quality. Again, this revision adds flexibility.

FDA disagrees with the comment that manufacturing materials should be deleted from this section. Section 820.70(e) requires procedures to ensure that manufacturing materials do not become contaminated. Section 820.70(g), in contrast, establishes requirements related solely to the equipment used in the manufacturing process, and § 820.70(h), ''Manufacturing material,'' addresses requirements for the removal or limitation of manufacturing materials. Thus, § 820.70 (g) and (h) are distinct and are intended to achieve different objectives.

131. The only two comments received on proposed § 820.70(f), ''Sewage and refuse disposal,'' recommended that it be deleted because it was unnecessary and/or covered by other Federal regulations.

Section 820.70(f) has been deleted because the requirements are adequately covered in the current requirements under § 820.70(e), ''Contamination control,'' and § 820.70(c), ''Environmental control.'' Under these sections, sewage, trash, byproducts, chemical effluvium, and other refuse that could affect a device's safety, effectiveness, or fitness-for-use must be adequately controlled.

132. Two comments stated that the requirement related to equipment in § 820.70(g) should ensure that equipment meets ''specified requirements,'' not be ''adequate for its intended use,'' because intended use is determined during the design phase, and because it is easier to assess whether equipment meets specified requirements.

From these comments, FDA can see that the requirement should be revised because it may have been misinterpreted. The requirement is reworded as suggested. Under the requirement, the equipment must be appropriately designed to facilitate maintenance, adjustment, cleaning, and use. It must also meet the requirements that are necessary to ensure its proper functioning for the manufacture of the device.

133. A few comments stated that not all equipment requires maintenance, and the requirement for a maintenance schedule in § 820.70(g)(1) should be revised to make that clear. The GHTF recommended that the second sentence of proposed § 820.70(g)(1), which required that the maintenance schedule be posted or readily available, be deleted and placed in guidance.

FDA agrees that not all equipment may require maintenance and notes that the general requirement of § 820.70(a) requires process control procedures that describe only those controls which are necessary. Therefore, FDA did not revise the requirement.

FDA has deleted the requirement that the maintenance schedule be posted or readily available. Section 820.70(g), which directs a manufacturer to ensure that equipment meets specified requirements, requires that the manufacturer ensure that maintenance is carried out on schedule to comply with the requirement. To satisfactorily meet this requirement, FDA expects that the schedule will be posted on or near the equipment to be maintained, or otherwise made readily available to appropriate personnel. Deletion of the requirement, however, permits the manufacturer added flexibility in complying with this section.

134. Several comments stated that § 820.70(g)(2), ''Inspection,'' and (g)(3), ''Adjustment,'' should be deleted and placed in guidance because the requirements are adequately covered in § 820.70(g)(1). Another comment stated that the requirement for limitations or tolerances to be ''visibly posted on or near equipment'' should be deleted.

FDA believes that to adequately ensure that equipment continues to meet its specifications, and to ensure that inherent limitations and allowable tolerances are known, these requirements are imperative. FDA notes inherent limitations and allowable tolerances must be visibly posted on or near equipment *or* made readily available to personnel to allow the manufacturer the flexibility to utilize any system to make sure that the limitations or tolerances are readily available to the personnel that need them. Both § 820.70(g)(2) and (g)(3) are requirements in the original CGMP regulation and the agency has found them to be useful and necessary.

135. One comment stated that requiring the removal of manufacturing material to be documented in proposed § 820.70(g)(4), ''Manufacturing material,'' would result in impossible requirements, such as the requirement to document how much cutting oil is lost during a metal removing operation, such as drilling. Others commented that the requirement needs to be amended to clarify that only manufacturing materials that have an adverse effect or that are unwanted need to be removed or limited.

FDA disagrees with the first comment because § 820.70(g)(4) (now § 820.70(h)) only requires that the fact that manufacturing material was removed or reduced be documented, not how much was removed or how much was lost due to processing. This requirement is carried over from the original CGMP regulation, § 820.60(d). FDA has amended the section, however, to clarify that this requirement is necessary ''Where a manufacturing material could reasonably be expected to have an adverse effect on product quality.'' FDA

purposefully qualifies the general requirement by that which adversely affects ''*product quality*'' (product as defined in § 820.3(r)) and limits the requirement for removal or reduction to ''an amount that does not adversely affect the *device's quality*.''

136. One comment on § 820.70(h), ''Automated processes,'' (now § 820.70(i)), stated that the section should be revised to reflect that software used in such systems must be validated for ''its intended use,'' not simply validated. Another comment stated that most companies buy software currently available on the market and do not make changes to the software. It was recommended that § 820.70(h) allow for use of outside personnel for validation runs and not necessarily require the development of a software validation procedure. One comment suggested that the section should allow verification rather than validation of off-the-shelf software. Several comments on ''automated processes'' stated that the term ''data processing systems'' was unclear and its inclusion rendered the requirement too broad. Others asked for clarification of ''automated data processing systems.''

FDA has modified the requirement to mandate validation for the intended use of the software. In addition, the requirement that the software be validated by individuals designated by the manufacturer has also been deleted to make clear that validation may be performed by those other than the manufacturer. However, whether the manufacturer designates its own personnel or relies on outside assistance to validate software, there must be an established procedure to ensure validation is carried out properly.

FDA has maintained the requirement for validation because the agency believes that it is necessary that software be validated to the extent possible to adequately ensure performance. Where source code and design specifications cannot be obtained, ''black box testing'' must be performed to confirm that the software meets the user's needs and its intended uses.

FDA emphasizes that manufacturers are responsible for the adequacy of the software used in their devices, and activities used to produce devices. When manufacturers purchase ''off-the-shelf'' software, they must ensure that it will perform as intended in its chosen application.

FDA has amended the requirement to state ''When computers or automated data processing systems are used as part of production or the quality system,'' for clarification. Software used in production or the quality system, whether it be in the designing, manufacturing, distributing, or tracing, must be validated.

ii. Inspection, Measuring, and Test Equipment (§ 820.72)

137. A few comments stated that it is unclear what is meant by the requirement in proposed § 820.84 *Inspection, measuring, and test equipment* that equipment be capable of producing ''valid results.'' The comments stated that such equipment may be ''suitable for its intended purpose'' and still not always ''produce valid results.''

FDA believes that the term ''valid results'' is commonly understood and notes that it has been in the original CGMP regulation under § 820.61 for 18 years. The requirement is for the equipment to work properly, thereby providing ''valid results.''

FDA renumbered § 820.84 as § 820.72 in response to comments that stated these requirements were more appropriate under subpart G Production and Process Controls. FDA revised the requirement in new § 820.72(a), ''Control of inspection, measuring, and test equipment,'' to make clear that the procedures must also ensure that the equipment is maintained and moved the requirement that the procedure include provisions for handling, preservation and storage of equipment from § 820.84(d) in the Working Draft to § 820.72(a). FDA deleted the term ''test software'' that was in § 820.84(e) because FDA believes that ''test software'' is now covered under ''electronic inspection and test equipment'' in § 820.72(a).

138. A few comments stated that the last sentence in proposed § 820.84(a), ''Calibration,'' is unnecessary because the requirement for trained personnel is redundant with § 820.25(a) *Personnel.* A few comments stated that FDA should identify what must be remedied in proposed § 820.84(a).

FDA agrees that the requirement for trained personnel is redundant and has deleted this sentence from § 820.72(b), ''Calibration.'' FDA has also added to this section the requirement that the calibration procedure include provisions for remedial action to ''reestablish the limits and to evaluate whether there was any adverse effect on the device's quality'' to clarify this remedial action requirement and its relationship to the requirements in § 820.100 *Corrective and preventive action.*

139. Several comments stated that § 820.84(b), ''Calibration standards,'' should allow for the use of international standards.

FDA agrees and has rewritten the section, now § 820.72(b)(1), ''Calibration standards,'' to allow the use of international standards. The standards used must be generally accepted by qualified experts as the prevailing standards.

140. FDA has deleted the requirement in proposed § 820.84(c), now § 820.72(b)(2), ''Calibration records,'' that calibration records be ''maintained by individuals designated by the manufacturer'' because, on further reflection, the agency believes such a requirement is unnecessary. As long as the required procedures and records are maintained and displayed or readily available as required, the objective of the section, ensuring that calibration is performed and acceptable, will be met. FDA did add ''equipment identification'' to the list of items that had to be documented in response to a comment that requested clarification in this regard, so that equipment is clearly identified in the calibration records even if the records are not displayed on or near the particular piece of equipment.

141. Two comments suggested deleting proposed § 820.84(d) because they believed it was unnecessary to establish procedures to maintain equipment, because most manufacturers simply store equipment in protective covers.

As already noted, FDA has moved the requirement for establishing maintenance procedures into the general requirement in § 820.72. FDA has retained the requirement because some equipment requires special handling, preservation, and storage. For example, the temperature and humidity of a room may affect the equipment and procedures would need to be established taking those factors into account.

142. Several comments stated that proposed § 820.84(e), ''Facilities,'' should be deleted because it is redundant with the requirements under § 820.70(g) and the general requirements of proposed § 820.84(a).

FDA agrees that revised § 820.84(a), which is now § 820.72(a), would require procedures to ensure that equipment is protected from adjustments that could invalidate the calibration, in that the section requires procedures to ensure that equipment is properly maintained. The procedures that require equipment to be routinely calibrated, inspected, and checked, will also ensure that improperly calibrated equipment is not used. Therefore, FDA has deleted proposed § 820.84(e).

iii. Process Validation (§ 820.75)

143. A few comments on proposed § 820.75 *Special processes* stated that the meaning of the term ''special processes'' was unclear. Other comments stated that FDA should provide examples of processes that would be considered ''special processes.'' Several comments stated the term ''fully verified'' was unclear and should be deleted.

In response to the comments, the term ''special processes'' has been dropped from the regulation and the term ''process validation'' is defined in § 820.3(z)(1). The section now requires that when a process ''cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance. * * *'' Examples of such processes include sterilization, aseptic processing, injection molding, and welding, among others. The validation method must ensure that predetermined specifications are consistently met. The new § 820.75, entitled ''Process validation,'' is consistent with ISO 9001:1994, section 4.9, including the terminology ''fully verified.'' FDA does not believe this terminology is unclear since it has been used in ISO 9001:1987 and 1994 and explained in several guidance documents.

FDA amended this section by removing the requirement for the signature of the individual(s) performing the process and placing the signature requirement on the approval of the validation where FDA believes it is more important and appropriate. FDA also added that ''where appropriate, the major equipment validated'' must be documented. Depending on the process that is validated, it may be necessary to document the person performing the process or the equipment or both in order to have adequate controls on the process.

144. Several comments were received on proposed § 820.75(a)(1) through (a)(4) that stated that the requirements were redundant with other parts of the regulation and should be modified or deleted.

FDA disagrees with the comments and believes that, due to the importance of process validation and correct performance of the validated process, the requirements are necessary. The requirements have been rearranged in the revised section.

145. Comments on the first sentence of proposed § 820.75(b) stated that it was unclear and unrealistic. Other comments stated that the requirement for continuous monitoring is not practical or necessary.

In response to the comments, FDA has revised the requirements. Section 820.75(b) applies to the performance of a process *after* the process has been validated. In contrast, § 820.75(a) relates to the initial validation of the process. FDA deleted the term ''continuous'' because the agency concurs that monitoring can be accomplished at a determined interval and frequency depending on the type of validated process being monitored and controlled. FDA notes that the interval and frequency should be periodically evaluated for adequacy, especially during any evaluation or revalidation that occurs in accordance with the requirements in new § 820.75(c).

New § 820.75(b)(1), which was proposed § 820.75(c) of the Working Draft, requires that validated processes be performed by a qualified individual(s). FDA notes that § 820.75(b)(1) is similar to the requirements under § 820.25 *Personnel* but emphasizes that validated processes must not only be performed by personnel with the necessary education, background, training, and experience for their general jobs but must be performed by personnel qualified for those particular functions. Revised § 820.75(b)(2), which was proposed § 820.75(d) of the Working Draft, contains the amended documentation requirements for validated processes, to include the monitoring and control methods and data. FDA notes that it is always ''appropriate'' to document the equipment used in the process where the manufacturer uses different equipment on different manufacturing lines. To investigate a problem with the device, the manufacturer will need to know which equipment was used, since the problem could be with the equipment itself. The same holds true for the individual(s) performing the process.

Section 820.75(c) contains requirements on process revalidation in response to several comments and concerns on when revalidation activities were necessary. FDA believes that the new arrangement of § 820.75 should clarify the requirement.

H. Acceptance Activities (Subpart H)

i. Receiving, In-Process, and Finished Device Acceptance (§ 820.80)

146. One comment stated that the emphasis on testing and inspection in proposed § 820.80 completely ignores the quality goals, the benefit of requiring purchasing controls, and statements made in the preamble of the proposal reflecting FDA's negative opinion about manufacturers relying solely on testing and inspection. A few comments on the Working Draft stated that ''acceptance activities'' should be defined as inspections, tests, or other verification activities so that the regulation does not require all of these activities but gives the manufacturer the flexibility to choose the appropriate method.

FDA agrees with the comments and has replaced the term ''inspection and test'' with ''acceptance activities'' in § 820.80. Further, FDA now defines ''acceptance activities'' to include inspections, test, or other verification activities, such as supplier audits.

147. One comment stated that recordkeeping is a significant cost factor in the operation of a total quality system, and that the revised CGMP regulation should not add cost through duplication of documentation. The comment said recording all quantitative data is inappropriate and of little value.

FDA agrees that unnecessary duplication of documentation should be avoided. FDA believes that the quality system regulation requires the minimum documentation necessary to ensure that safe and effective devices are designed and produced. FDA similarly believes that maintaining records of results of acceptance activities is imperative to ensure that nonconforming product is not inadvertently used or distributed. FDA has, however, deleted from § 820.80(a) the requirement for recording the results of inspections and testing because § 820.80(e) requires that the results of acceptance activities be recorded. The requirement in § 820.80(a) was therefore unnecessary. Further, the regulation does not specify quantitative data but simply requires that the results be recorded. FDA believes that it is essential for the manufacturer to maintain records which provide evidence that the product has gone through the defined acceptance activities. These records must clearly show whether the product has passed or failed the acceptance activities according to the defined acceptance criteria. Where product fails to pass acceptance activities, the procedures for control of nonconforming product must be implemented, to include investigations where defined. If the acceptance records are not clear about how the product failed, then the manufacturer may end up duplicating the acceptance activities in order to perform appropriate investigations.

148. Several comments stated that proposed § 820.80(b), ''Receiving inspection and testing,'' did not allow for urgent use of incoming items. The comments said that urgent use should be permitted if forward traceability is maintained so that recall and

replacement is possible if the material is subsequently found to be nonconforming. One comment stated that the requirements in proposed § 820.80(b) were too specific and did not allow flexibility.

FDA agrees in part with the comments. FDA has permitted manufacturers to use incoming items that had not yet been proven acceptable for use, provided that the manufacturer maintained control of the unapproved items and could retrieve the product that contained the unapproved items *before* distribution. Therefore, the requirement that product ''shall not be used or processed until * * * verified'' has been deleted from § 820.80(b), now entitled ''Receiving acceptance activities.'' However, FDA emphasizes that while the product can be used in production prior to verification, it *cannot* be distributed prior to verification. FDA does not permit the distribution of unapproved product through an urgent use provision, because all finished devices must comply with § 820.80(d), ''Final acceptance activities,'' before they are released for distribution.

In addition to the changes noted above, FDA has deleted the requirement that ''individual(s) designated by the manufacturer shall accept or reject incoming'' product. FDA does not believe this requirement is necessary in § 820.80(b) because § 820.80(e) requires that the identification of the individual(s) conducting the acceptance activities be recorded.

149. Several comments stated that an absolute requirement under proposed § 820.80(c), ''In-process inspection and testing,'' for in-process testing was inconsistent with the preamble, which stated that an appropriate mix of controls should be established. Other comments stated that in-process inspection and testing is unnecessary if the process is validated and the devices are subject to final inspection. A few comments on the Working Draft stated that the term ''held'' was too restrictive and was not consistent with the requirements and the preamble discussion for § 820.80(b).

FDA agrees with the comments in part, but believes that § 820.80 as now written, with the inclusion of ''where appropriate,'' does not mandate in-process inspection and testing. FDA acknowledges that in-process acceptance activities may not be necessary or possible for every device, for example, medical socks. Further, the requirement states that in-process product must be *controlled* until the required inspection and test, or other verification activities, have been performed. This will permit manufacturers to use, under defined conditions and procedures, product that has not *completed* the acceptance activities described in § 820.80(b) and (c). This does not means that manufacturers can ignore the requirements in § 820.80(b) and (c) because these requirements must be completed in order to comply with § 820.80(d), which must be satisfied before devices are released for distribution.

150. FDA received a similar comment on proposed § 820.80(d), ''Final inspection and test,'' which said that the provision requires finished device inspection for all devices, without defining what inspection is expected. The comment suggested that § 820.80(d) could be interpreted to require actual product inspection, which has been shown to be ineffective as a means of controlling product quality. One comment stated that signatures should not be the only approved method for identification of the individual(s) responsible for release. The comment stated that use of inspection stamps and initials should be allowed.

FDA has rewritten § 820.80(d) to require that manufacturers establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets specified requirements. Manufacturers have the flexibility to choose a combination of methods, including finished device inspection and test, provided such methods will accomplish the required result.

FDA believes that it is important for the person responsible for release to have personally documented and dated that release. This can be accomplished through use of an inspection stamp, if the stamp is controlled as discussed above under § 820.40 *Document controls.* Therefore, FDA has retained the requirement for a signature.

151. Several comments on proposed § 820.80(e), ''Inspection and test records,'' stated that manufacturers should not be required to record the use of general equipment in inspection and test records, because this requirement would be burdensome to large manufacturers who use many common pieces of equipment. A few comments stated that the record requirements under § 820.80(e) are overly prescriptive and go well beyond ISO 9001's comparable requirements. The comments stated that recordkeeping should be specified by the manufacturer in the spirit of ISO 9001, and should include only the minimum records necessary to show that finished device inspections are performed in accordance with established procedures.

FDA agrees that it may not be necessary to document every piece of equipment used in acceptance activities. The requirement, renamed ''Acceptance records,'' now provides that equipment used shall be documented ''where appropriate.'' For some critical operations and testing, identification of the equipment used will be imperative for proper investigations into nonconforming product.

The requirements, as revised, are similar to those in ISO 9001:1994. As discussed above, certain information must be captured on acceptance records for the records to be useful in evaluating nonconformance. Through many years of experience, FDA has determined what it believes to be a minimum requirement for these records. Section 820.80(e) reflects that determination.

ii. Acceptance Status (§ 820.86)

152. Several comments on proposed § 820.86, ''Inspection and test status,'' stated that the section was not flexible enough to allow identification of the inspection and test status of product by various means, because the requirement was for the status to be ''visible.'' One comment questioned why ''component acceptance'' was addressed separately.

FDA agrees that the inspection and test status may be identified by any method that will achieve the result, which might include acceptable computerized identification, markings, etc. The section has been rewritten to reflect this intent, has been renamed ''Acceptance status,'' and is now consistent with ISO 9001:1994. FDA also agrees that ''component acceptance'' is covered by ''manufacturing'' and has deleted the term.

153. FDA has deleted proposed § 820.86(b) which required that records identify those responsible for release of the product, because the agency believes that the records required by § 820.80(e) will identify those responsible for release of product.

I. Nonconforming Product (Subpart I)

154. FDA has rewritten § 820.90 *Nonconforming product* to utilize the term ''product'' throughout, as defined in § 820.3(r), for both shorthand purposes and consistency with ISO 9001:1994.

155. One comment suggested deleting the term ''inadvertently'' and adding the word ''distributed'' before ''installed'' in § 820.90(a). Several written comments and persons who testified at the August and September 1995 meetings stated that § 820.90(a) should be written so

that it is not interpreted to require investigations for every nonconformance. A few comments stated that the term ''provide for'' was too broad and unclear. Other comments stated that the requirement to ''ensure'' nonconforming product was ''not used or distributed'' was inconsistent with the provisions in § 820.90(b) which allowed for concessions under certain circumstances. One comment stated that the requirement that persons responsible for nonconforming product be ''notified'' should be deleted because it is overly burdensome and not needed in all cases.

FDA has reworded the general requirement for procedures to control nonconforming product and has deleted the term ''inadvertently.'' FDA has also added the requirement that the procedures provide for the ''evaluation'' of nonconforming product because evaluation is key to protecting against recurring nonconformance. The addition is consistent with ISO 9001:1994.

FDA has further revised § 820.90 in response to the comments on the Working Draft. First, the manufacturer must establish procedures to ''control'' nonconforming product. Second, the procedures shall ''*address* the identification, documentation, evaluation, segregation, and disposition of nonconforming product,'' which gives the manufacturers the flexibility to define how they are going to ''control'' products that are nonconforming. Third, the evaluation process addressed in the procedure ''shall include a determination of the need for an investigation.'' Therefore, the procedures will need to set forth the manufacturer's SOP on when investigations will take place and provisions for trending and/or monitoring the situation in the future. Fourth, FDA added ''The evaluation and any investigation shall be documented,'' which would include the explanations for not performing investigations and how nonconformances will be trended and/or monitored. Further, the phrase ''is not used or distributed'' has been deleted to be consistent with § 820.90(b).

FDA disagrees that the notification requirement should be deleted. Where some person or organization is responsible for nonconformances, they must be notified to ensure that future nonconformances are prevented. This requirement is also in ISO 9001:1994, section 4.13.1.

156. FDA has rewritten § 820.90(b)(1), ''Nonconformity review and disposition,'' to make clear that the section requires procedures that define the responsibility for review and authority for disposition of nonconforming product and that set forth the review and disposition process. FDA believes that proper disposition of nonconforming product is essential for ensuring the safety and effectiveness of devices. Manufacturers have made determinations that nonconforming product may be used which have resulted in defective devices being distributed. Thus, although it may be appropriate at times to use nonconforming products, the disposition process must be adequately controlled.

The revision requires that disposition and justification for concessions be documented. FDA believes that the justification should be based on scientific evidence, which a manufacturer should be prepared to provide upon request. Concessions should be closely monitored and not become accepted practice. This section is consistent with ISO 9001:1994, section 4.13.2.

Several comments on the Working Draft stated that the term ''concession'' should be deleted because it is confusing. FDA has rewritten the sentence to ensure the meaning of this requirement is clear. The sentence now reads, ''Documentation shall include the justification for the use of nonconforming product and the signature of the individual(s) authorizing the use.''

157. Several comments were received on proposed § 820.90(b)(2). One comment stated that the requirement should allow for other types of disposition besides reprocessing. One comment suggested replacing the term ''reinspection'' with ''evaluation,'' to allow for greater flexibility in verification methods. Many comments suggested that the requirement for identification of reprocessed product should be deleted because they believed it would cause the consumer to forego purchasing the product. Several comments requested that the term ''rework'' be used instead of ''reprocessing'' to harmonize terminology with ISO standards.

FDA agrees in part with the comments. FDA, as noted in the definition section, has substituted the term ''rework'' and the ISO 8402:1994 definition for the term ''reprocessing'' in response to the comments. FDA believes that the revised § 820.90(b)(1) clearly allows for other methods of disposition besides rework. Section 820.90(b)(2), which governs rework when it is chosen as a method of disposition, has been revised as requested by replacing the term ''reinspection'' with ''reevaluation.'' The change will allow manufacturers the flexibility to inspect or use other verification activities.

FDA has also deleted the requirement for identification of reworked product from this section because FDA believes that it is adequately covered in §§ 820.60 *Identification* and 820.86 *Acceptance status*.

Other minor changes made to the section include requiring that a determination of any adverse effect of the rework upon the product be made, whether there is ''repeated'' rework or not. FDA's intent is that such a determination be made with any rework, given the potential harmful effect rework could have on the product. The change harmonizes § 820.90 with ISO/CD 13485. In addition, the sentence requiring a ''complete reinspection'' for reworked product was deleted because the section already requires retesting and reevaluation of reworked product. FDA has also substituted ''current'' for ''original or subsequently modified'' approved specifications for clarity. The requirements as written are consistent with the original CGMP requirements in §§ 820.115 and 820.116.

J. Corrective and Preventive Action (Subpart J)

158. A few comments suggested revising proposed § 820.100 *Corrective and preventive action* to require procedures for implementing corrective and preventive action, consistent with ISO 9001. One comment stated that the procedures should provide for an initial halt of distribution of suspect products or tight control and action concerning products already distributed before taking the long term action listed in this section.

FDA agrees that it is essential that the manufacturer establish procedures for implementing corrective and preventive action and has revised § 820.100(a) accordingly. The procedures must include provisions for the remaining requirements in the section. These procedures must provide for control and action to be taken on devices distributed, and those not yet distributed, that are suspected of having potential nonconformities.

159. Other comments stated that the degree of remedial action should be commensurate with the risk associated with a product failure.

FDA agrees that the degree of corrective and preventive action taken to eliminate or minimize actual or potential nonconformities must be appropriate to the magnitude of the problem and commensurate with the risks encountered. FDA cannot dictate in a regulation the degree of action that

should be taken because each circumstance will be different, but FDA does expect the manufacturer to develop procedures for assessing the risk, the actions that need to be taken for different levels of risk, and how to correct or prevent the problem from recurring, depending on that risk assessment.

FDA emphasizes that any death, even if the manufacturer attributes it to user error, will be considered relevant by FDA and will have a high risk potentially associated with it. User error is still considered to be a nonconformity because human factors and other similar tools should have been considered during the design phase of the device. FDA acknowledges that a manufacturer cannot possibly foresee every single potential misuse during the design of a device, but when the manufacturer becomes aware of misuse, the corrective and preventive action requirements should be implemented to determine if redesign of the device or labeling changes may be necessary.

160. Several comments on proposed § 820.100(a)(1) stated that requiring a manufacturer to analyze ''all'' processes, work operations, and other factors listed, is excessive and unrealistic. Some comments stated that there should not be a requirement to conduct an analysis for ''potential causes'' of nonconformances. A few comments stated that including ''quality audits'' in the list was inconsistent with the FDA policy of not reviewing internal audits. A few comments stated that the requirement that the analysis include ''trend analysis'' should be modified because it places unnecessary emphasis on only one statistical method or tool. Other comments stated that statistical tools are not always necessary and that the requirement should be modified.

FDA agrees in part with the comments. It was not FDA's intent to require that processes unrelated to an existing nonconformity be analyzed. Instead, § 820.100(a)(1) requires an analysis of those items listed that could be related to the problem. To prevent confusion, the word ''all'' has been deleted. The requirement is similar to that of ISO 9001:1994, section 4.14.3(a).

The inclusion of ''quality audits'' as a valuable feedback mechanism for the manufacturer does not conflict with FDA's policy of not reviewing internal quality audits. Internal audits are valuable and necessary tools for the manufacturer to evaluate the quality system. The audit reports should be used to analyze the entire quality system and provide feedback into the system to close the feedback loop, so that corrective or preventive actions can be taken where necessary. FDA will review the corrective and preventive action procedures and activities performed in conformance with those procedures without reviewing the internal audit reports. FDA wants to make it clear that corrective and preventive actions, to include the documentation of these activities, which result from internal audits and management reviews are not covered under § 820.180(c).

FDA has further revised the requirement to delete the reference to trend analysis in response to the comments. The provision now requires that ''appropriate statistical methodology'' be employed where necessary to detect recurring quality problems. This revision is made because there may be other statistical tools available beyond ''trend analysis.'' FDA emphasizes that the *appropriate* statistical tools must be employed when it is necessary to utilize statistical methodology. FDA has seen far too often the misuse of statistics by manufacturers in an effort to minimize instead of address the problem. Such misuse of statistics would be a violation of this section.

FDA has retained the requirement for analysis to identify ''potential causes of nonconforming product,'' however, because FDA believes this is an important aspect of preventive action. FDA notes that ISO 9001:1994, section 4.14.1, specifically acknowledges that corrective and preventive actions are associated with actual and *potential* nonconformities.

161. Several comments stated that proposed § 820.100(a)(2) was redundant with requirements in § 820.198 *Complaints*.

FDA agrees in part with the comments and has written the section to require investigation of the cause of nonconformities relating to process, product, and the quality system, consistent with ISO 9001:1994, section 4.14.2(b). The requirement in this section is broader than the requirement for investigations under § 820.198, because it requires that nonconforming product discovered before or after distribution be investigated to the degree commensurate with the significance and risk of the nonconformity. At times a very indepth investigation will be necessary, while at other times a simple investigation, followed by trend analysis or other appropriate tools will be acceptable. In addition, in contrast to § 820.198, the requirement in this section applies to process and quality system nonconformities, as well as product nonconformities. For example, if a molding process with its known capabilities has a normal 5 percent rejection rate and that rate rises to 10 percent, an investigation into the nonconformance of the process must be performed.

162. One comment stated that proposed § 820.100(a)(3) should not require identification of action necessary to correct ''other quality problems.'' Another stated that the section should be harmonized with ISO. One comment thought that the requirement should be to identify action to correct problems identified by ''trend analysis.''

FDA agrees that harmonization is important and has harmonized the terminology (and intent) of the section with ISO 9001:1994, sections 4.14.2(c) and 4.14.3(b). However, FDA disagrees that the section should not require identification of action necessary to correct ''other quality problems'' because the objective of § 820.100 is to correct and prevent poor practices, not simply bad product. Correction and prevention of unacceptable quality system practices should result in fewer nonconformities related to product. Therefore, this section addresses problems within the quality system itself. For example, it should identify and correct improper personnel training, the failure to follow procedures, and inadequate procedures, among other things.

FDA also disagrees with the suggestion to link the requirement in § 820.100(a)(3) to trend analysis and has deleted the reference to trend analysis in § 820.100(a)(1) to give the manufacturer the flexibility to use whatever method of analysis is appropriate.

163. FDA has revised § 820.100(a)(4) to reflect that preventive, as well as corrective, action must be verified or validated. The section is now consistent with ISO 9001:1994, sections 4.14.2(d) and 4.14.3(c). Two comments stated that the definitions of validation and verification cause confusion here, but FDA believes that these concerns should be resolved with the amended definitions under § 820.3 (z) and (aa).

164. FDA has also revised § 820.100(a)(5) in the same manner, to relate the requirements to preventive action. This section is consistent with ISO 9001:1994, section 4.14.1, third paragraph.

165. One comment suggested that proposed § 820.100(a)(6) be revised to reflect that minor quality problems may not need to be disseminated to those directly responsible for ensuring quality and to be reviewed by management.

FDA agrees in part with this comment. The revised § 820.100 (a)(6) and (a)(7) require that procedures ensure that information is disseminated to those directly responsible for assuring quality or the prevention of such problems, and provide for submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review. This revision should address the concern raised by the comment because only certain information need be directed to management. The manufacturer's procedures should clearly define the criteria to be followed to determine what information will be considered ''relevant'' to the action taken and why. FDA emphasizes that it is always management's responsibility to ensure that all nonconformity issues are handled appropriately. This section is now consistent with ISO 9001:1994, section 4.14.3(d).

166. Two comments stated that the records required under § 820.100(b) should be treated as part of the internal audit.

FDA disagrees with these comments because this information is directly relevant to the safety and effectiveness of finished medical devices. FDA has the authority to review such records and the obligation to do so to protect the public health. Comparable information and documentation is reviewed by the FDA under the requirements of the original CGMP, §§ 820.20 (a)(3) and (a)(4) and 820.162. Manufacturers will be required to make this information readily available to an FDA investigator, so that the investigator may properly assess the manufacturer's compliance with these quality system requirements.

K. Labeling and Packaging Control (Subpart K)

i. Device Labeling (§ 820.120)

167. Several comments on proposed § 820.162 *Device labeling* stated that the section should be deleted and placed in guidance because it is unnecessary and redundant with requirements under §§ 820.80 and 820.86. A few comments stated that the section should be changed to be the same as that in the original CGMP regulation, under §§ 820.120 and 820.121. Another comment stated that labeling and packaging requirements should be in subpart K of part 820 and handling, storage, distribution, and installation requirements should be in subpart L of part 820 because labeling and packaging functionally occur before distribution and installation.

FDA believes that the section, as written, is consistent with the requirements in the original CGMP. Section 820.120 relates specifically to labeling and its requirements are in addition to those in both §§ 820.80 and 820.86. Further, FDA believes that the degree of detail in this section is necessary because these same requirements have been in place for 18 years, yet numerous recalls every year are the result of labeling errors or mixups. FDA therefore believes that more, not less, control is necessary.

FDA has reordered the subparts but notes that the handling and storage requirements apply throughout the production process.

168. One comment stated that ''to maintain labeling integrity and to prevent labeling mixups'' should be deleted from the general requirement because the requirements are detailed in the following sections. Other comments stated that all labels need not be affixed to the device and others stated that ''legible and affixed'' may not be appropriate for all implantable devices.

FDA agrees with the comments and has revised the requirements accordingly.

169. A few comments stated that what is now § 820.120(b), ''Labeling inspections,'' should allow automated readers to be used in place of a ''designated individual(s)'' to examine the labeling.

FDA disagrees with the comments because several recalls on labeling have been attributed to automated readers not catching errors. The requirement does not preclude manufacturers from using automated readers where that process is followed by human oversight. A ''designated individual'' must examine, at a minimum, a representative sampling of all labels that have been checked by the automated readers. Further, automated readers are often programmed with only the base label and do not check specifics, such as control numbers and expiration dates, among other things, that are distinct for each label. The regulation requires that labeling be inspected for these items prior to release.

170. FDA has amended § 820.120(b) to add ''any'' to additional processing instructions in response to a comment for clarity. FDA has amended § 820.120(d) to include ''The label and labeling used for each production unit, lot, or batch shall be documented in the DHR'' in response to comments questioning whether the labeling used should be recorded in the DMR or the DHR. FDA also amended § 820.120(e) by adding ''or shall accompany the device through distribution'' and deleting ''itself or its label'' for clarity.

171. A few comments on proposed § 820.165 *Critical devices, labeling* stated that this section should be deleted to eliminate any distinction between critical and noncritical devices.

FDA agrees in part and has deleted § 820.165, but has added the requirement on control numbers to § 820.120(e).

ii. Device Packaging (§ 820.130)

172. Two comments on proposed § 820.160 *Device packaging* stated that the section should be changed to allow manufacturers to use third parties, if desired, for packaging. Another comment stated that it is very difficult if not impossible to protect from intentional damage, such as tampering.

FDA agrees with the comments and has changed the requirement, now in § 820.130, accordingly. FDA believes, however, that any intentional tampering would not be covered because the requirement states ''during customary conditions.''

L. Handling, Storage, Distribution, and Installation (Subpart L)

i. Handling (§ 820.140)

173. One comment on proposed § 820.120 *Handling* suggested that the procedures be ''designed to prevent,'' rather than be established to ''ensure that,'' problems delineated in the section do not occur. The comment stated that the word ''prevent'' would add clarity, without compromising the meaning of the sentence. Another comment stated that the handling procedures should apply ''prior to distribution,'' not during ''any stage of handling.'' One comment stated that the requirement does not cover the need for special precautions in handling used devices which may be contaminated, and that this is an important issue covered by ISO/CD 13485.

FDA does not believe that § 820.120, now § 820.140, as written is unclear. The procedures are expected to ensure that mixups, damage, deterioration, contamination, or other adverse effects do not occur. FDA amended the requirement, however, to remove ''any stage of'' so it reads ''during handling.'' The requirement continues to apply to all stages of handling in which a manufacturer is involved, which may in some cases go beyond initial distribution.

The comparable provision in ISO/CD 13485 states, ''If appropriate, special provisions shall be established, documented and maintained for the handling of used product in order to prevent contamination of other product, the manufacturing environment and

personnel.'' FDA agrees with this requirement and has therefore added the term ''contamination'' to §§ 820.140 *Handling* and 820.150 *Storage.*

ii. Storage (§ 820.150)

174. Two comments stated that proposed § 820.122 *Storage* should be amended to be similar to ISO 9001, and that the rest of the requirements should be deleted and included in a guidance document. One comment stated that the term ''obsolete'' should be deleted because, although a device may no longer be sold, thereby making it obsolete, the components for that device may still be stored for customer support of the existing devices.

FDA agrees that § 820.122, now § 820.150, could be more consistent with ISO 9001 and has revised the section to harmonize with ISO 9001:1994. FDA has not deleted the term ''obsolete.'' FDA understands that a device may no longer be sold, but that parts and subassemblies may still be required for customer support; therefore, those components or subassemblies are not ''obsolete.'' FDA's intent in this requirement is to ensure that only the appropriate product be used or distributed.

FDA has deleted the requirement that control numbers or identifications be legible and visible because it believes the requirement is inherent in § 820.150(a), which requires the manufacturer to establish procedures to prevent mixups. To do this, a manufacturer must ensure that product can be properly identified.

175. A comment stated that restricting access to designated areas through the use of keys, bar code readers, or other means, should be sufficient to meet the intent of the requirement in proposed § 820.122(b), without the need for written procedures for authorizing receipt.

FDA has not deleted the requirement for procedures, now in § 820.150(b), to authorize receipt of product because the agency believes that strict control over product in storage areas and stock rooms results in decreased distribution of nonconforming product. Thus, even where locked storage rooms are utilized, the procedures should detail, among other things, who is permitted access and what steps should be followed prior to removal.

iii. Distribution (§ 820.160)

176. A few comments on proposed § 820.124 *Distribution* stated that there are times when ''first in, first out'' inventory procedures may not be in the best interest of the customer. The comments said that especially when expiration dating is defined and labeled, a ''first in, first out'' system should not be required. The GHTF and other EU comments stated that if a new section ''Contract review,'' similar to ISO 9001:1994, section 4.3 was not added to the regulation, the requirement that ''purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution'' should be added to this section.

FDA agrees with the comments. FDA has amended the requirement in § 820.160 to state that the procedures must ensure that ''expired devices or devices deteriorated beyond acceptable fitness for use'' are not distributed. FDA has also added the sentence on reviewing purchase orders.

177. A few comments on proposed § 820.124(b) stated that class I devices should be exempt, or that the requirement should apply only to critical devices, because all devices do not require control numbers. Other comments stated that the term ''consignee'' should be defined, or the word ''primary'' should be added before ''consignee'' for clarity.

FDA agrees in part with the comments and in § 820.160(b) has added the term ''initial'' before ''consignee'' to make clear that the requirement for maintaining distribution records extends to the first consignee. FDA has retained the word ''consignee'' and notes that it is a person to whom the goods are delivered. FDA has also clarified § 820.160(b)(4) by requiring ''Any control number(s) used.'' Therefore, if the manufacturer is required by § 820.65 to have control numbers, these must be recorded along with any control numbers voluntarily used. Logically, control numbers are used for traceability so they should be recorded in the DHR distribution records. FDA disagrees, however, that the requirement to maintain distribution records should not apply to class I devices. The information required by this section is basic information needed for any class of product in order to conduct recalls or other corrective actions when necessary.

iv. Installation (§ 820.170)

178. Several comments received on proposed § 820.126, *Installation* stated that not all devices require installation. Several comments on the Working Draft asked that, ''The results of the installation inspection shall be made available to FDA upon request'' be deleted because this was redundant with FDA's access to these documents under § 820.180.

FDA agrees with the first set of comments. As discussed in § 820.1, the installation requirements only apply to devices that are capable of being installed. However, to further clarify the requirements in § 820.170, FDA has made clear that the requirement applies to ''devices requiring installation.'' FDA also agrees that the sentence on document availability is redundant with § 820.180 for all records and has deleted the sentence.

179. Several comments raised the issue of applying the regulation requirements to third party installers.

FDA has rewritten § 820.170. Persons who install medical devices have been regulated under the original CGMP under § 820.3(k) which describes a manufacturer as one who ''assembles or processes a finished medical device,'' and continue to be regulated under this quality system regulation under § 820.3(o). Section 820.152 *Installation* of the original CGMP discussed the manufacturer or its authorized representative and persons other than the manufacturer's representative. This regulation eliminates that terminology. Under the revised requirement in § 820.170(a), the manufacturer establishes installation and inspection instructions, and where appropriate test procedures. The manufacturer distributes the instructions and procedures with the device or makes them available to person(s) installing the device. Section 820.170(b) requires that the person(s) installing the device follow the instructions and procedures described in § 820.170(a) and document the activities described in the procedures and instructions to demonstrate proper installation.

The revised provisions in § 820.170(b) explicitly require that the installation be performed according to the manufacturer's instructions, regardless of whether the installer is employed by or otherwise affiliated with the manufacturer. Section 820.170(b) requires records to be kept by whomever performs the installation to establish that the installation was performed according to the procedures. Such records will be available for FDA inspection. FDA does not expect the manufacturer of the finished device to maintain records of installation performed by those installers not affiliated with the manufacturer, but does expect the third party installer or the user of the device to maintain such records.

FDA believes that making these requirements explicit in the regulation is necessary to ensure that devices are safe and effective, and that they perform as intended after installation. FDA notes

again that installers are considered to be manufacturers under the original CGMP regulation and that their records are, and will continue to be, subject to FDA inspections when the agency deems it necessary to review such records.

M. Records (Subpart M)

i. General Requirements (§ 820.180)

180. Several comments under § 820.180 *General requirements* suggested that FDA delete the requirement that records be stored to allow ''rapid retrieval'' because a reasonable time frame should be allowed. One comment stated that the wording of the section needed to be amended to allow records to be located in different places, especially for foreign manufacturers and distributors. Two comments stated that the requirement should be qualified by ''subject to conflicting legal requirements in other countries'' because some countries have ''blocking statutes'' that would prohibit the release of some information. One comment stated that wherever the word ''all'' appeared in the requirements, FDA should remove it.

FDA has rearranged this section, and notes that records must be kept in a location that is ''reasonably accessible'' to both the manufacturer and FDA investigators, and that records must be made ''readily available.'' FDA expects that such records will be made available during the course of an inspection. If the foreign manufacturer maintains records at remote locations, such records would be expected to be produced by the next working day or 2, at the latest. FDA has clarified that records can be kept at other than the inspected establishment, provided that they are made ''readily available'' for review and copying. This should provide foreign manufacturers and initial distributors the necessary flexibility.

FDA has not qualified § 820.180 in response to the comments on the ''blocking statues'' because if manufacturers want to import medical devices into the United States, then they must comply with applicable statutory and regulatory requirements, including part 820. The records section of this regulation is essentially the same as that of the original CGMP and FDA has not found these ''blocking statutes'' to present a problem. Further, countries increasingly realize the importance of a global market, thus FDA does not anticipate this issue to be a problem in the future.

In response to the comment on the term ''all'', FDA notes that where a requirement exists for ensuring that records are maintained in a certain fashion, a manufacturer must keep *all* records subject to the regulation in that manner. The revised section makes clear that it is ''all records required'' by the regulation to which the section's requirements pertain.

181. A few comments on § 820.180(b), ''Record retention period,'' stated that the section should be amended because all quality records may not be tied to a specific device; therefore, such quality records may not need to be maintained over the lifetime of a device. A few comments stated that the retention period requirement is unclear and burdensome, while others stated that the period should be left to the manufacturer to define. One comment suggested the deletion of the requirements related to photocopying records in proposed § 820.180(b) because it is technology that is not necessarily being used.

FDA believes that all records should be retained for a period equivalent to the design and expected life of the device, but in no case less than 2 years, whether the records specifically pertain to a particular device or not. The requirement has been amended to make clear that all records, including quality records, are subject to the requirement. FDA believes this is necessary because manufacturers need all such records when performing any type of investigation. For example, it may be very important to access the wording of a complaint handling procedure at the time a particular complaint came in when investigating a trend or a problem that extends to several products or over an extended period of time. Further, FDA does not believe that allowing the manufacturer to define the retention period will serve the public's best interest with regard to safety concerns and hazard analysis.

In response to the comment on photocopying, FDA has deleted the last two sentences. The agency believes that this requirement is outdated and does not necessarily reflect the technology being utilized today. Section 820.180 requires that records be readily available for inspection and copying by FDA, and FDA will interpret ''copying'' to include the printing of computerized records, as well as photocopying.

182. One comment on proposed § 820.180(c) stated that all quality audit reports should be subject to FDA review and public disclosure. A few other comments stated that for a management representative to certify that ''corrective action has been taken'' would be difficult because some corrective actions are long term and may not be completed at the time of certification.

FDA disagrees with the comment that quality audit reports should be subject to FDA review for the reasons given in the preamble of the original CGMP regulation, published in the Federal Register on July 21, 1978 (43 FR 31508), and believes that the disclosure of the audit reports themselves would be counterproductive to the intent of the quality system. FDA has added § 820.180(c), ''Exceptions,'' to address which records FDA, as a matter of policy, will not request to review or copy during a routine inspection; such records include quality audit reports. FDA may request an employee in management with executive responsibility to certify in writing that the management reviews, quality audits, and supplier audits (where conducted) have been performed, among other things. FDA may also seek production of these reports in litigation under applicable procedural rules or by inspection warrant where access to the records is authorized by statute. Again, FDA emphasizes that its policy of refraining from reviewing these reports extends only to the specific reports, not to the procedures required by the sections or to any other quality assurance records, which will be subject to review and copying.

FDA agrees with the comments on the timing of corrective actions and has amended the certification requirement to state ''corrective action has been undertaken.''

ii. Device Master Record (DMR) (§ 820.181)

183. A few comments on proposed § 820.181 *Device master record* stated that the requirement for a ''qualified'' individual to prepare the DMR should be deleted because it is unclear or redundant with the requirements in § 820.25.

FDA has not deleted the requirement for the DMR to be prepared, dated, and approved by a qualified individual because the agency believes this is necessary to assure consistency and continuity within the DMR. The section is consistent with the original CGMP, § 820.181. FDA has, however, substituted the phrase ''prepared and approved in accordance with § 820.40'' to be consistent with the requirements already in § 820.40 and to eliminate any redundancy.

184. Two comments on § 820.181(a) stated that ''software design specifications'' should not be included in the DMR because these documents will be located in the DHF. Another comment requested that the requirement that the DMR contain ''software source code'' information be amended because

source codes for commercialized software will not be available to the device manufacturers. Another comment stated that the source code should not be in the DMR because it will already be in the DHF.

FDA deleted the reference to ''software source code'' because this is already covered with the requirement for ''software specifications.'' The final software specifications should be transferred into production. Therefore, the final software specification for the particular device or type of device should be located or referenced in the DMR, while any earlier version should be located or referenced in the DHF. FDA believes that it is more important for manufacturers to construct a document structure that is workable and traceable, than to worry about whether something is contained in one file as compared to another. The DMR is set up to contain or reference the procedures and specifications that are current on the manufacturing floor. The DHF is meant to be more of a historical file for utilization during investigations and continued design efforts.

185. One comment on § 820.181(c) stated that the DMR should not contain quality system documents, but rather the quality control documents related to the specific device. Three comments stated that validation and verification information belongs in the DHF, not the DMR.

FDA agrees in part with the comments and has revised the section to clarify that the quality records required in the DMR relate to the specific current design, not the more general requirements of the quality system, which are addressed under new § 820.186. However, the comments are incorrect that all validation and verification information is related solely to design. There are requirements for validation and verification pertaining to device processing that may be better kept in the DMR instead of the DHF. The documentation of such verification and validation activities relating to processes that are performed for several different devices or types of devices can be placed or referenced in the location that best suits the manufacturer. Again, it is more important that the manufacturer store and retrieve information in a workable manner, than keep such information in particular files.

186. FDA notes that the regulation contains a few requirements which apply ''where appropriate'' or ''at appropriate stages.'' FDA emphasizes that the procedures that the manufacturer places in the DMR must clearly define the requirements the manufacturer is following and when particular activities are appropriate. The manufacturer will have failed to comply with the requirements of the section if the procedures simply state that the review or activity occurs at ''appropriate stages.''

The same principle applies for every section of this regulation, which is written to be flexible enough to cover the manufacture of all types of devices. Manufacturers must adopt quality systems appropriate for their specific products and processes. In establishing these procedures, FDA will expect manufacturers to be able to provide justifications for the decisions reached.

iii. Device History Record (§ 820.184)

187. One comment on § 820.184 stated that labeling should not be required in the DHR because it is already required in the DMR. Another comment stated that some devices have 25 or more labels and that only the primary identification labels are necessary in the DHR. One comment stated the requirement should be amended because it explicitly requires that dates and quantities for each batch be in the DHR, while only implying through the general requirement that the DHR must also contain the batch test data.

FDA agrees that it may not be necessary to include all labeling used in the DHR. However, FDA continues to believe, as it explained in the preamble to proposed regulation published in the Federal Register on November 23, 1993 (58 FR 61952 at 61968), that increased control over labeling is necessary due to the many labeling errors resulting in recalls. Therefore, FDA has retained a requirement related to labeling in the DHR, but revised it to make it less burdensome. The requirement was amended to ''the primary identification label and labeling'' which is consistent with that contained in the original CGMP regulation, § 820.185. FDA believes that the requirement that the DHR contain the primary label and labeling used for each production unit, coupled with the labeling controls in § 820.120, should help to ensure that proper labeling is used and, hopefully, decrease the number of recalls due to improper labeling.

FDA agrees with the last comment and has added in § 820.184 ''(d) The acceptance records which demonstrate the device is manufactured in accordance with the DMR'' to explicitly state the requirement to avoid any confusion.

188. FDA has deleted the requirement for the DHR to be ''readily accessible and maintained by a designated individual(s)'' because it believes that the objective of that requirement is met through §§ 820.40 *Document controls* and 820.180 *General requirements.*

FDA has also added ''device identification'' to the requirement under § 820.184(f) because it believes that any identification or control number used should be documented in the DHR to facilitate investigations, as well as corrective and preventive actions. FDA notes that this provision does not add any requirement for identification or traceability not already expressed in §§ 820.60 and 820.65.

iv. Quality System Record (§ 820.186)

189. Several comments stated that the regulation should more closely harmonize with ISO 9001:1994. A few comments stated that the regulation should include the requirements for a quality manual. One comment stated that general quality system procedures and instructions should not be required in the DMR because the DMR is device specific, and many quality system procedures are not tied to a particular device.

FDA agrees in part with these comments and has developed new § 820.186 *Quality system record.* This section separates the procedures and documentation of activities that are not specific to a particular type of device from the device specific records.

v. Complaint Files (§ 820.198)

190. Two comments on proposed § 820.198 *Complaint files* stated that the requirements were very detailed and that much of the language should be placed in a guidance document.

FDA disagrees with the comments. These requirements are essentially the same as the original CGMP requirements under § 820.198, and 18 years of experience with these requirements shows that many manufacturers still do not understand and properly handle complaints. Therefore, FDA believes that the amount of detail in § 820.198 is appropriate and necessary. In an effort to make the requirements more clear, however, the section has been reorganized to better illustrate how complaint information should be handled.

Section 820.198(a) sets forth the general requirement for establishing and maintaining a complaint handling procedure and includes a few items that the procedure needs to address. Section 820.198(b) discusses the initial review and evaluation of the complaints in order to determine if complaints are ''valid.'' It is important to note that this evaluation is not the same as a complaint investigation. The evaluation

is performed to determine whether the information is truly a complaint or not and to determine whether the complaint needs to be investigated or not. If the evaluation decision is not to investigate, the justification must be recorded. Section 820.198(c) then describes one subset of complaints that must be investigated, but explains that duplicative investigations are not necessary. In cases where an investigation would be duplicative, a reference to the original investigation is an acceptable justification for not conducting a second investigation. Section 820.198(d) describes another subset of complaints that must be investigated (those that meet the MDR criteria) and the information that is necessary in the record of investigation of those types of complaints. Section 820.198(e) sets out the type of information that must be recorded whenever complaints are investigated. The information described in § 820.198 (e)(1) through (e)(5) would most likely be attained earlier in order to perform the evaluation in § 820.198(b). This information need not be duplicated in the investigation report as long as the complaint and investigation report can be properly identified and tied together. Section 820.198 (e)(1) through (e)(5) are considered to be basic information essential to any complaint investigation. If there is some reason that the information described in § 820.198(e) cannot be obtained, then the manufacturer should document the situation and explain the efforts made to ascertain the information. This will be considered to be acceptable as long as a reasonable and good faith effort was made. For example, a single phone call to a hospital would not be considered by FDA to be a reasonable, good faith effort to obtain information. Section 820.198(f) is the same as § 820.198(d) of the original CGMP, where the manufacturing facility is separate or different from that of the formally designated complaint handling unit. In such cases, it is important that the facility involved in the manufacturing of the device receive or have access to complaint and investigation information. In order to give manufacturers the flexibility of using computer or automated data processing systems, the term ''reasonably accessible,'' from § 820.180, is used. Section 820.198(g) is the complaint recordkeeping requirement for distributors. In order to give manufacturers the same flexibility as described in § 820.198(f), FDA has included ''reasonably accessible'' in § 820.198(g).

Throughout § 820.198, when there is reference to the MDR regulation or to the types of events that are reportable under the MDR regulation, this section simply refers to events or complaints that ''represent an event which is required to be reported to FDA under part 803 or 804 of this chapter.''

191. A few comments on § 820.198(a) stated that the section should allow for more than one ''formally designated unit'' to handle complaints, especially for large corporations where it would not be feasible or beneficial for all divisions to have a single complaint handling unit. A few other comments stated that § 820.198(a)(2) on oral complaints should be deleted because it is too subjective.

FDA disagrees with these comments. Large corporations may have different complaint handling units for different product types or different manufacturing establishments. However, there should be only one formally designated complaint handling unit for each product type or establishment. If a corporation chooses to operate with different complaint handling units for products and/or establishments, the manufacturer must clearly describe and define its corporate complaint handling procedure to ensure consistency throughout the different complaint handling units. A system that would allow multiple interpretations of handling, evaluating, categorizing, investigating, and following up, would be unacceptable. Each manufacturer should establish in its procedures which one group or unit is ultimately responsible for coordinating all complaint handling functions.

FDA also disagrees that the requirement that oral complaints be documented upon receipt should be deleted. A December 1986 General Accounting Office (GAO) report entitled ''Medical Devices; Early Warning of Problems Is Hampered by Severe Underreporting,'' (Ref. 11) showed that approximately 83 percent of the hospitals report complaints orally. FDA believes that these oral complaints must be captured in the complaint handling process.

192. FDA, as noted above, has added to § 820.198(c) the phrase ''unless such investigation has already been performed for a similar complaint and another investigation is not necessary'' to clarify that duplicative investigations are not required if the manufacturer can show that the same type of failure or nonconformity has already been investigated.

193. Several comments on proposed § 820.198(b), now § 820.198(d), stated that the evaluation of complaints pertaining to death, injury, or hazard to health should be removed from this section because it is redundant with the MDR regulation. Several other comments on § 820.198(b) stated that complaints pertaining to death, injury, or hazard to health need not be maintained separately, as long as they are identified.

FDA disagrees that the requirements are redundant, but believes that they expressly state what is expected in the handling of this type of complaint information. The requirements have been moved to a separate section, § 820.198(d).

FDA agrees with the second set of comments and has revised the section to permit such complaints to be ''clearly identified.'' This will give a manufacturer flexibility in choosing a means of ensuring that these types of complaints can be immediately recognized and segregated for purposes of prioritizing and meeting other requirements.

FDA has substituted the term ''promptly'' for the term ''immediately'' to be more consistent with the new MDR regulation timeframes. FDA has also clarified that § 820.198 (d)(1) through (d)(3) are in addition to the information that must be recorded in § 820.198(e).

194. A few comments on proposed § 820.198 (c) and (d) stated that FDA should make clear that some of the requirements will not always be applicable. For example, the comments stated that a record of corrective action cannot be made if such action is not required, and is not taken.

Where corrective action is not necessary and is not taken, it cannot be documented. The section was revised to make that clear. As stated in the preamble to the proposal (58 FR 61952 at 61968), the manufacturer's procedures should clearly identify when corrective action will be taken.

In addition, FDA combined provisions in § 820.198 (c) through (e) to eliminate redundancy and added the requirement that the records include any device identification, as well as control number used, to facilitate corrective and preventive actions. FDA has also deleted the term ''written'' in § 820.198(e) to be consistent with FDA's statements on electronic and computer systems.

195. FDA deleted the requirements in proposed § 820.198(f) in response to comments because it agrees that it is not necessary to repeat the requirements of the MDR regulation in the quality system regulation. Section 820.198(a) requires that all complaints be evaluated to determine whether they are subject to

the requirements of the MDR regulation under part 803 or 804.

196. A few comments on proposed § 820.198(g), now § 820.198(f), stated that duplicate records are not needed in this age of computer systems, and that the requirement as written would be counterproductive.

FDA agrees with the comments and has rewritten the section to allow the complaints and records of investigation to be reasonably accessible at the formally designated complaint unit and the manufacturing site, where these locations are distinct. A manufacturer's procedures must ensure that the manufacturing site is alerted to complaints concerning devices produced at that site.

197. Several comments on proposed § 820.198(h), now § 820.198(g), stated that the requirement is unnecessary, given that FDA can inspect a foreign manufacturer that imports devices, and is burdensome.

FDA has revised the section to permit the records to be reasonably accessible, similar to § 820.198(f), which should alleviate any burden. However, the agency must have access to these records in the United States.

198. Several comments on proposed § 820.198 (i) and (j) stated that the requirements should be deleted because they are redundant with the MDR requirements in part 803.

FDA disagrees that all of the requirements in § 820.198 (i) and (j) are redundant. The requirement that procedures ensure that complaints are processed uniformly and in a timely manner, and evaluated to determine whether they are reportable under part 803 or 804, has been moved up to § 820.198(a). These are basic requirements for complaint handling. If the complaint is determined to be of the type subject to part 803 or 804, those requirements apply. The requirements of parts 803 and 804 are not repeated in this regulation. FDA has deleted § 820.198(j).

N. Servicing (Subpart N)

199. Numerous comments were received on the servicing requirements that were proposed. Many of these comments dealt with competitive issues between manufacturers that perform or contract out their own servicing and third party service organizations. The comments received, as well as the recommendations from the GMP Advisory Committee, were split on many issues. Therefore in this regulation, FDA has chosen to codify only longstanding requirements for servicing performed by original manufacturers and remanufacturers. The requirements in § 820.200 are similar to those in ISO 9001:1994, with some supplemental requirements for clarification on monitoring service reports, on the relationship of service reports and complaints, and on the type of information FDA believes is essential in any service report. As described above in the definition section of this preamble, a separate rulemaking will specify and clarify the requirements for third party service organizations.

200. Other comments on proposed § 820.200(a) stated that it is impractical to return a used device to its original specifications because a certain amount of wear and tear should be expected, without detriment to the safety and effectiveness of the device. Several comments on § 820.200(a) stated that the term ''records'' should be replaced by ''reports,'' to be consistent with ISO 9001.

FDA agrees and has revised the requirements in § 820.200(a) to be similar to the requirements in ISO 9001:1994 as recommended by comments at the GMP Advisory Committee meeting to require that the servicing instructions and procedures ensure that the device will meet ''specified requirements'' for the device's intended use. FDA is aware that with use and age, a device may be serviced to function as intended, but may not meet original specifications.

FDA agrees with the comments and has modified the language in § 820.200(b), (c), and (d) to use the term ''service reports.''

201. A few comments on proposed § 820.200(b), ''Service report evaluation,'' questioned whether full corrective action was necessary for every service report and whether service calls need to be handled as complaints only when there is a death, injury, or hazard to safety.

FDA has rewritten this section into § 820.200(b) and (c) to clarify the agency's intent and to use terms consistent with those used in § 820.198. Section 820.200(b) now states that ''Each manufacturer shall analyze service reports with appropriate statistical methodology in accordance with § 820.100.'' Full corrective action may not be required for every service report. However, if the analysis of a service report indicates a high risk to health, or that the frequency of servicing is higher than expected, the remainder of the corrective and preventive action elements are applicable, in accordance with the corrective and preventive action procedures established under § 820.100.

Section 820.200(c) provides that when a service report ''represents an event which must be reported to FDA under part 803 or 804 of this chapter,'' it is automatically considered by FDA to be a complaint that must be handled according to § 820.198. FDA emphasizes that this provision is not intended to limit ''complaints'' to MDR reportable events.

202. FDA has also added in § 820.200(d) the requirements for recording the name of the device, any device identification(s) and control number(s) used, as well as test and inspection data, because FDA believes such documentation in the service report will facilitate investigations. This additional documentation provision does not add any requirement for identification or traceability not already expressed in §§ 820.60 and 820.65. Therefore, § 820.200(d) as amended focuses on the type of information that should be captured on the service report instead of where the information should be sent.

O. Statistical Techniques (Subpart O)

203. FDA amended § 820.250(a) to be consistent with the requirements in ISO 9001:1994, section 4.20.

204. Several comments on § 820.250(b) stated that the provision as written seems to require the use of sampling plans, and that every manufacturer does not necessarily use sampling plans. Another comment stated that sampling plans are not often used during reviews of nonconformities, quality audits, or complaints, and that these examples should, therefore, be deleted. Two other comments questioned the meaning of ''regularly reviewed.''

FDA's intent was not to require the use of sampling plans, but to require that where they are used, they should be written and valid. Section 820.250 was revised to make that clear. Sampling plans are not always required, but any time sampling plans are used, they must be based on a valid statistical rationale. Further, FDA acknowledges that the most common use of sampling plans is during receiving acceptance, and has deleted the examples. FDA has also clarified the review requirement by stating ''to ensure that when changes occur the sampling plans are reviewed.''

VI. Summary of Changes From the July 1995 Working Draft to the Final Rule and Rationale

Note: Minor changes to improve grammar, readability, and clarity, as well as changes in terminology and organization for the sake of consistency throughout the regulation, are not listed.

A. Section 820.1 Scope

1. Inserted sentence, ''If a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged'' for further clarification of the scope in response to many comments.

2. Amended sentence on component manufacturers to read, ''This regulation does not apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidance'' as a result of the many written comments and oral testimony at the August and September 1995 meetings.

3. Inserted sentence on how to interpret the phrase ''where appropriate'' in the regulation, as recommended by the GMP Advisory Committee. This sentence is consistent with International Organization for Standards (ISO)/CD 13485—''Application of Quality Systems to Medical Devices.''

B. Section 820.3 Definitions

4. Amended the definition of *Complaint* by inserting ''after it is released for distribution'' in response to comments for clarification and to harmonize with ISO/CD 13485.

5. Amended the definition of *Component* by deleting ''packaging'' for clarification that every piece of packaging is not necessarily a component, only the materials that are part of the ''*finished, packaged, and labeled device*.''

6. Amended the definition of *Design output* to clarify its relationship with the Device Master Record.

7. Amended the definition of *Design review* to delete ''and propose the development of solutions'' in order to allow the manufacturer the flexibility to determine whom the appropriate person(s) is to propose solutions.

8. Deleted the definition of *End of life* in response to the many written comments and oral testimony at the August and September 1995 meetings.

9. Amended the definition of *Manufacturer* to delete component manufacturers and to remove the terms ''*servicer*'' and ''*refurbisher*.'' The obligations of servicers and refurbishers will be addressed in a separate rulemaking later this year. The terms ''*installation*'' and ''*remanufacturing*'' were added to codify longstanding FDA policy and interpretations of the original CGMP regulation.

10. Amended the definition of *Manufacturing material* in response to comments requesting clarification and separation of examples.

11. Deleted the definition of *Record* to avoid confusion. *Record* will continue to be defined by the act and case law.

12. Removed the definition of *Refurbisher* for reasons discussed in paragraph 28, section V.A. of this document.

13. Inserted the definition of *Remanufacturer* for reasons discussed in paragraph 28, section V.A. of this document, and made the language consistent with that of the 510(k) provision and the PMA amendment/supplement requirements.

14. Changed the term *Reprocessing* to *Rework* and adopted a definition consistent with ISO 8402 Quality Management and Assurance Vocabulary Standard in response to comments for closer harmonization of terminology.

15. Removed the definition of *Servicing*, and *Servicer* which was proposed to the GMP Advisory Committee, for reasons discussed above.

16. Amended the definition of *Validation* as recommended by the GMP Advisory Committee for further clarity by delineating the terms validation, process validation, and design validation.

17. Amended the definition of *Verification* for further clarity in response to comments and to more closely harmonize with ISO 8402.

C. Section 820.5 Quality System

18. Deleted the requirements in § 820.5(a) and (b) because these requirements are now found in § 820.20.

D. Section 820.20 Management Responsibility

19. Moved the requirements from § 820.186 and rewrote into new § 820.20(d) and (e) for clarity, better organization, and closer harmonization with ISO/CD 13485.

E. Section 820.25 Personnel

20. Inserted the phrase, ''establish procedures for identifying training needs'' in § 820.25(b) in response to comments to add this requirement and to harmonize with the requirement in ISO/CD 13485.

21. Deleted the sentence in § 820.25 on understanding the ''CGMP requirements applicable to their job function'' to provide manufacturers with the flexibility to appropriately train personnel.

F. Section 820.30 Design Controls

22. Amended the requirements in *Design and development planning* for clarity and to more closely harmonize with ISO/CD 13485.

23. In § 820.30(c), inserted the sentence, ''The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements'' in response to comments to add this requirement and to harmonize with the requirement in ISO/CD 13485.

24. In § 820.30(d), deleted the sentence, ''Design output procedures shall ensure that design output meets the design input requirements'' because this was redundant with the requirement in § 820.30(f) *Design verification*.

25. Amended § 820.30(e) *Design review* to clarify that the procedures shall ensure that an independent person is included in design reviews.

26. Section 820.30(f) *Design verification and validation* was split into two paragraphs, (f) *Design verification* and (g) *Design validation* and the requirements were separated between the two paragraphs, in response to many written comments and oral testimony at the August and September 1995 meetings and to improve clarity and consistency with ISO/CD 13485.

27. Amended the requirement for § 820.30(i) *Design changes* to add the phrase ''before their implementation'' due to an inadvertent omission in the July 1995 Working Draft.

G. Section 820.50 Purchasing Controls

28. Deleted the last two sentences in § 820.50(b) and inserted ''Purchasing data shall be approved in accordance with *§ 820.40*'' because the last two sentences were redundant with the requirements in § 820.40.

H. Section 820.65 Traceability

29. Substituted the definition of critical device from the original CGMP for the phrase ''where necessary to ensure the protection of the public health,'' in response to many comments requesting clarification as to when traceability is necessary.

30. Added ''where appropriate'' for the traceability of components in response to the recommendation of the GMP Advisory Committee, the written comments, and to harmonize with ISO/CD 13485.

I. Section 820.70 Production and Process Controls

31. Inserted ''identified and approved'' in § 820.70(a)(5) before ''representative samples'' to clarify that the samples have to be established and deemed appropriate before they are used as a standard.

32. Substituted in § 820.70(b) ''where appropriate validated according to § 820.75'' for ''unless inspection and test

fully verifies the results of the changes'' because it was redundant with the requirements set forth in § 820.75.

33. Amended the requirement in § 820.70(c) to apply only ''Where environmental conditions could reasonably be expected to have an adverse effect on product quality,'' in response to comments and to be consistent with the original CGMP requirements.

34. Amended the requirements in § 820.70(d) and (e) to include ''could reasonably be expected to have an adverse effect on product quality'' to consistently qualify when these provisions are appropriate.

35. Amended the requirement in § 820.70(h) to apply only ''Where a manufacturing material could reasonably be expected to have an adverse effect on product quality,'' in response to comments and to be consistent with the original CGMP requirements.

36. Rearranged the wording in § 820.70(i) to clarify ''automated data processing systems.''

J. Section 820.72 Inspection, Measuring, and Test Equipment

37. Renumbered § 820.84 as § 820.72 for better organization because *Inspection, measuring, and test equipment* requirements are more appropriate under Subpart G—Production and Process Controls than under Subpart H—Acceptance Activities.

38. Section 820.72(b) ''Calibration standards'' and (c) ''Calibration records'' were reorganized as paragraphs(1) and (2), respectively under paragraph (b) ''Calibration.''

39. Amended § 820.72(b) to include provisions for remedial action to ''reestablish the limits and to evaluate whether there was any adverse effect on the device's quality'' in response to comments which questioned whether this was adequately covered under § 820.100.

40. Section 820.84(d), ''Maintenance,'' is reorganized into § 820.72(a) ''Control of inspection, measuring, and test equipment'' and ''test software'' is deleted because it is considered to be covered under ''electronic inspection and test equipment'' in the general requirement.

K. Section 820.75 Process Validation

41. Section 820.75(a) is amended for clarity. The phrase ''with a high degree of assurance'' was deleted from the definition of ''Validation'' and added as a requirement under process validation.

42. Section 820.75(b)(2) was amended to state ''where appropriate, the individual(s) performing the process or the major equipment used'' in response to comments requesting that flexibility be given to the manufacturer to determine when these items needed to be documented.

43. Section 820.75 (c) and (d) were redesignated as paragraphs (b)(1) and (b)(2) for better organization and flow.

44. Section 820.75(c) was added to address comments and concerns on when revalidation activities were necessary.

L. Section 820.80 Receiving, In-process, and Finished Device Acceptance

45. Section 820.80(c) was amended to add ''where appropriate'' to reinforce the discussion in the preamble that in-process testing is not always necessary depending upon the type of device and the manufacturing set-up.

M. Section 820.90 Nonconforming Product

46. Amended the requirement in § 820.90(a) to include, ''The evaluation of nonconformance shall include a determination of the need for an investigation * * *. The evaluation and any investigation shall be documented.'' in response to many written comments and oral testimony at the August and September 1995 meetings on whether every nonconformance had to be investigated.

47. Amended the requirement in § 820.90(b)(1) to read, ''Documentation shall include the justification for use of nonconforming product'' in response to several comments confused about the meaning of the term ''concession.''

48. In § 820.90(b)(2), substituted the term ''rework'' for the term ''reprocessing'' for reasons described in the definitions section.

49. Deleted the sentence, ''Reprocessed product shall be clearly identified during reprocessing, and shall be subjected to reevaluation'' in § 820.90(b)(2) because the requirement was redundant with the requirements in §§ 820.60 *Identification* and 820.86 *Acceptance status*.

N. Section 820.100 Corrective and Preventive Action

50. Amended § 820.100(a)(7) to clarify what information is to be submitted to management for review.

O. Section 820.120 Device Labeling

51. Inserted ''where appropriate'' before ''use'' in § 820.120(a) because every device may not have a label directly affixed to the device itself (e.g. implantable devices).

52. Inserted the sentence, ''The label and labeling used for each production unit, lot, or batch shall be documented in the DHR'' into § 820.120(d) in response to comments questioning whether the labeling used should be recorded in the device master record or the device history record.

P. Section 820.160 Distribution

53. Inserted the requirement in § 820.160 ''that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution'' in response to the GHTF comments and other EU comments that the regulation did not address the requirements in ISO 9001, section 4.3, ''Contract Review.''

Q. Section 820.170 Installation

54. Amended the installation requirements for clarity and deleted the last sentence in § 820.170(b), ''The results of the installation inspection shall be made available to FDA upon request'' because this sentence is redundant with the requirements in § 820.180 for all records.

R. Section 820.181 Device Master Record (DMR)

55. In § 820.181 deleted the phrase ''dated, and signature of the qualified individual(s) designated by the manufacturer'' and inserted ''and approved in accordance with § 820.40'' to be consistent with the requirements already in § 820.40.

56. In § 820.181 deleted the phrase ''and software source code for customized software'' because comments stated that this was already covered with the requirement for ''software specifications.''

S. Section 820.186 Quality System Record (QSR)

57. Amended the requirement in § 820.186 by adding the sentence,

> The QSR shall include, or refer to the location of, procedures and the documentation of activities required by this part that are not specific to a particular type of device(s), including but not limited to the records required by § 820.20. Each manufacturer shall ensure that the QSR is prepared and approved in accordance with § 820.40.

Deleted the requirements in § 820.186(a) through (d) because those requirements are now found in § 820.20. This change was in response to comments and suggestions made by the GHTF for further harmonization with ISO/CD 13485 and for clarity.

T. Section 820.198 Complaint Files

58. In § 820.198 deleted the terminology ''pertaining to death,

injury, or any hazard to safety'' throughout this section and inserted ''an event which must be reported to the FDA under part 803 or 804 of this chapter'' to reference the MDR regulation.

59. Added the phrase ''unless such investigation has already been performed for a similar complaint and another investigation is not necessary'' in § 820.198(c) in response to comments which thought a second investigation was always mandated by this requirement.

60. Amended § 820.198(d) by changing the word ''immediately'' to ''promptly'' to be consistent with the new MDR regulation. Added, ''In addition to the information required by § 820.198(e),'' to clarify that an investigation under § 820.198(d) was to include requirements under paragraphs (d)(1) through (d)(3) and under paragraphs (e)(1) through (e)(8).

61. Substituted the phrase ''*reasonably accessible*'' for ''*concurrently maintained*'' in § 820.198 (f) and (g) as recommended by the GMP Advisory Committee to clarify FDA's intent of allowing these records to be available in other media forms besides the hard copies which were previously required.

U. Section 820.200 Servicing

62. Amended § 820.200(a) to adopt language consistent with ISO/CD 13485, which was suggested at the GMP Advisory Committee meeting, in order to clarify the requirement and further harmonize.

63. Deleted the last two sentences in § 820.200(a) on providing information to third party servicers since this industry will be addressed in a separate rulemaking, as discussed above.

64. Section 820.200(d) was amended for clarity and to focus on the service report and what type of information should be captured on the report instead of where the information should be sent.

V. Section 820.250 Statistical Techniques

65. Amended § 820.250(b) by inserting the phrase, ''to ensure that when changes occur the sampling plans are reviewed'' in response to comments for clarification on when the plans needed to be reviewed.

VII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) and (a)(10) 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. Intergovernmental Partnership

The agency has analyzed this rulemaking in accordance with the principles and criteria set forth in Executive Order 12875, ''Enhancing the Intergovernmental Partnership'' and in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12875 states that no agency or executive department shall issue any regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government unless the Federal Government supplies funds necessary to comply with the mandate, or the agency provides the Office of Management and Budget (OMB) a description of the agency's consultation with affected State, local, and tribal governments, the nature of their concerns, any written communications submitted to the agency by such units of government, and the agency's position supporting the need to issue the regulation containing the mandate. Executive Order 12875 does not apply to this final rule because the regulatory requirements are not generally applicable to government facilities but to finished device manufacturers. The agency notes, however, that the membership of the advisory committee established to review this regulation and make recommendations to the agency on the feasibility and reasonableness of the regulation (GMP Advisory Committee) must include three members who are officers or employees of any State or local government or of the Federal Government, and that in 1995 this committee included two State government representatives and one Federal Government representative.

The agency has also examined the consistency of this final rule with the Unfunded Mandates Reform Act of 1995. The Unfunded Mandates Reform Act requires (in section 202) that agencies prepare an assessment 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 (adjusted annually for inflation). FDA believes that the private sector expenditures for this rule fall below $100 million annually but nonetheless, due to uncertainties of these estimates, the agency has prepared for the private sector an assessment of anticipated costs and benefits for the 1993 proposed rule and this final rule as described in section IX. of this document.

IX. Economic Impact

A. Summary

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. As explained in detail below, FDA finds that this final rule has an estimated total annual incremental cost of $81.9 million to the U.S. industry and an estimated average annual benefit of from $180 million to $220 million in lives saved and is economically significant under Executive Order 12866. Consequently, the agency has completed this full regulatory flexibility analysis which demonstrates that this rule is consistent with the principles set forth in the Executive Order and the Regulatory Flexibility Act, and also with the Unfunded Mandates Reform Act as described in section VIII. of this document. This analysis, together with the preamble published in the Federal Register and supporting analysis and materials, constitutes a final regulatory flexibility analysis. In addition, this document has been reviewed by OMB as an economically significant regulatory action under Executive Order 12866.

The detailed data for this analysis were developed by Eastern Research Group, Inc. (ERG), under contract to FDA and their two reports: ''Economic Analysis of the Proposed Revisions to the Good Manufacturing Practices Regulation for Medical Devices,'' and ''Addendum to the Final Report'' are on file at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

The objective of this rule is to reduce the number of fatalities and injuries attributable to defective medical devices. FDA finds that private market incentives do not adequately reduce the risk of design-related device failures because neither physicians nor consumers have all of the information needed to make adequate judgments of product quality and legal tort remedies are slow, inefficient, and extremely costly.

The changes to the CGMP regulation will require manufacturers to extend

their quality systems to include several new areas, such as design and purchasing, and to clarify or expand selected existing requirements. Several of the changes to the regulation make it more consistent with ISO 9001:1994 quality standards. The rule will affect all medical device establishments engaged in the design, manufacture, contract sterilization, and packaging of medical devices.

This analysis presents the costs and benefits of the final CGMP rule and reflects the differences between the proposed and final regulation. The complete methodology and preliminary economic analysis was presented in the November 1993 ERG report, ''Economic Analysis of Proposed Revisions to the Good Manufacturing Practices Regulation for Medical Devices''. While the proposed rule covered component manufacturers, the cost of compliance for such manufacturers was inadvertently omitted from the November 1993 ERG report. However, FDA has decided not to cover component manufacturers, therefore most of the preliminary analysis remains valid (e.g., estimates of labor and resource requirements, level of compliance, and number of firms remain the same for the final analysis, except where noted).

Based on the ERG study, the total annual incremental costs to the U.S. industry of the final CGMP regulation are estimated to be about $81.9 million. These costs are more than offset, however, by benefits to public health and by economic benefits to the medical device industry. FDA estimates that the benefits to public health will include 36 to 44 fewer deaths and 484 to 677 fewer serious injuries per year, which are attributed to design-related device failures. Studies on the value of a statistical-life have reported estimates ranging from $1.6 million to $8.5 million.[1] Assuming an economic value of $5 million per fatality avoided, the monetary value of saving 36 to 44 lives each year will be $180 to $220 million. Therefore, the value of the public health benefits of preventing deaths alone easily exceeds the cost of compliance even without estimating benefits from a reduced number of serious injuries. Moreover, additional economic benefits to medical device establishments will result from cost savings due to fewer design-related product recalls, better product quality, and greater productivity. In addition, medical device establishments exporting to the EU will greatly benefit from the harmonization of the CGMP regulation with the ISO 9001:1994 quality standards. Because the EU is adopting ISO 9001:1994 as a basis for its medical device manufacturing quality system, the harmonization of the two quality requirements will eliminate the need for device manufacturers to maintain different quality systems for each market.

FDA supports the international harmonization of standards and regulations governing medical devices and the eventual mutual recognition of CGMP inspections between major device markets. While full achievement of this goal is still in the future, the harmonization of quality standards is an important first step.

FDA believes in a step wise approach toward harmonization and eventual mutual recognition. For CGMP inspections or Quality System Conformity Assessments, these goals comprise four basic steps. First, the harmonization of quality system requirements is a fundamental building block of all future work in this area. FDA believes that by working with the GHTF, specifically Study Group #3 of the GHTF, it has developed a final rule that incorporates the harmonized quality system requirements which are recognized around the world. Second is the harmonization of regulatory auditing or compliance inspections. This work is currently underway in the GHTF in Study Group #4, which has developed one draft document entitled ''Guidelines For Regulatory Auditing Quality Systems of Medical Device Manufacturers,'' expected to be finalized in 1997. The third step is for harmonization of the policy, interpretation, and regulatory consequences of noncompliance with the quality system requirements in this rule and in counterpart requirements of other countries. Underlying these activities is an ongoing need for confidence building between the parties working towards mutual recognition. FDA believes that this regulation will provide a sound foundation for the goal of mutual recognition of inspections, a goal that will benefit industry, as well as the agency. The Health Industry Manufacturers Association has stated that reciprocity for quality assurance inspections could save the medical device industry millions of dollars as well as provide significant savings to governments.[2]

For individual establishments, the economic impact of the regulation will depend on a number of factors, such as the level of current compliance, the type of activities performed at the establishment, and the nature of the product. On average, the smaller establishments will bear a relatively greater economic burden.

B. Industry Profile

Firms in the medical device industry are heterogeneous. They vary in size, product type, product and process technology, and rate of new product introductions. There are over 7,000 medical device establishments involved in the production of approximately 4,000 different types of devices (Table 1). Sixty-two percent of these establishments are very small (fewer than 20 employees), while 27 percent are of medium-size (20 to 99 employees), 7 percent are large (100 to 249 employees), and 4 percent are very large (250 or more employees). These size categories were developed to reflect size categories within the medical device industry and differ from the Small Business Administration definition. Under the Small Business Administration definition, over 98% of all establishments would be small.

TABLE 1.—DISTRIBUTION OF AFFECTED ESTABLISHMENTS BY EMPLOYMENT SIZE

Type of establishment	Total [1]	Employment size [2]			
		Small (1–19)	Medium (20–99)	Large (100–249)	Very large (≥250)
Design and Production Manufacturer	5,415	3,323	1,414	415	265
Contract manufacturer	419	257	109	32	20
Specification developer	541	352	162	27	0
Repacker/relabeler	828	538	248	41	0

[1] Fisher, A.; Chestnut, L.; and Violette, D. (1989). ''The Value of Reducing Risks of Death: A Note on New Evidence.'' *Journal of Policy Analysis and Management, 8* (pp. 88–100).

[2] Gilmartin, R.V. (1992). ''The Benefits of Cooperation for Industry and Regulators Alike: A Global Perspective.'' Presented at the Third Annual Global Medical Device Conference, October 2.

TABLE 1.—DISTRIBUTION OF AFFECTED ESTABLISHMENTS BY EMPLOYMENT SIZE—Continued

Type of establishment	Total [1]	Employment size [2]			
		Small (1–19)	Medium (20–99)	Large (100–249)	Very large (≥250)
Contract sterilizer	34	22	10	2	0
Total	7,237	4,492	1,943	517	285

[1] Based on data from FDA's Registration and Listing Branch, 1992, adjusted to reflect 13 percent not required to register and 6 percent exempt from CGMP requirements.
[2] ERG (1993), Section 3.

C. Comments to November, 1993 Proposed Changes to the CGMP Regulation

A small percentage of the public comments on the November 1993 proposed regulation addressed the economic impact analysis. The majority of these comments made very general, nonspecific observations and therefore cannot be addressed directly. Many of these comments stated that FDA underestimated the regulatory burden that the proposed CGMP regulation would place on medical device manufacturers. Others stated that their companies would expend more than the per establishment estimated costs; some discussed the hiring of additional personnel to address the compliance requirements.

In developing the cost estimates for the 1993 proposal, ERG attempted to describe the labor hours (and associated costs) needed to achieve an acceptable minimum level of compliance with each requirement. These estimates took into account the incremental labor and capital resources that would be needed to progress from the existing compliance level to the new level required by the proposal. For individual establishments, the economic impact of the CGMP regulation would depend on a number of factors, such as the level of current compliance, the type of activities performed, and the nature of the product. Not surprisingly, those establishments that currently undertake relatively few of the activities to be required would incur greater compliance costs than the averages presented.

In the final rule, FDA has eliminated or modified several requirements to give medical device establishments greater flexibility in selecting compliance methods. In general, the words ''where appropriate'' were added to many requirements to make them less prescriptive and allow establishments to determine if or when they are appropriate for their product. For example, in § 820.65 *Traceability*, the final requirement allows the manufacturer to identify which components require traceability. In addition, many procedures may not need to be changed, only documented. To further minimize compliance costs, FDA intends to provide additional guidance materials. The DSMA currently offers guidance materials and regional seminars on CGMP matters.

1. Health Industry Manufacturers Association (HIMA)

HIMA commented that FDA understated the costs for personnel training, maintenance of new systems, documentation revisions, and operational costs.

ERG agrees that it did not fully address the initial training requirements in the cost analysis for the proposed CGMP regulation. New costs for initial training were included in the cost analysis for the final CGMP regulation. However, the existing CGMP regulation requires periodic training of personnel. Therefore no incremental costs for periodic training were estimated.

ERG did not change its cost estimate for quality system maintenance and procedure revisions. Estimates were made for the incremental compliance costs associated with an annual review of each new procedure, but these procedures would be revised only sporadically and probable estimates of their future costs would be small and could not be reasonably quantified.

ERG recognized that companies will incur incremental costs to use new procedures. Although a separate estimate of these operational costs was not made, they were incorporated into the estimates of the individual requirements where applicable.

2. Other General Comments

Some manufacturers of low-risk devices and some that have never experienced a product recall or MDR event questioned the merit and benefits of applying design controls to all products. In the proposed and final CGMP regulation, FDA exempted almost all class I devices because the public health benefits gained did not exceed the costs of implementation. However, FDA believes that all class II and III devices should be covered because their failure could adversely affect public health. Even firms with excellent past records put their consumers at future risk if their design systems are inadequate. ERG estimates that strict compliance to the final CGMP regulation will avert about 43 deaths and over 600 serious injuries per year. In addition, the literature on quality systems consistently states that firms implementing such systems, which begin with design controls, report cost savings in the long-run.

A number of comments argued that the proposed CGMP regulation would slow product innovation and increase health care costs. FDA believes that the gains from improvements in quality control and greater efficiencies will lessen the impact on both innovation and health care costs and will not lower the innovation rate for products with significant medical benefit. Manufacturers will also avoid the costs of most design-related medical device recalls. ERG estimated that design-related recalls cost industry approximately $40 million per year. Health care spending overall will also decrease as deaths, injuries and malfunctions from medical device failures decrease.

Some comments suggested that the proposed CGMP regulation would hurt the domestic medical device industry's competitiveness and encourage companies to move their operations to foreign countries. FDA has sought to harmonize the final CGMP regulation with ISO 9001:1994 and ISO/CD 13485. Some comments had stated they would like to see even greater harmonization in the final regulation. The harmonization of regulatory requirements will benefit medical device establishments because they will be able to maintain a single regulatory compliance program. The harmonization of CGMP requirements is also a first step in developing mutual recognition agreements between U.S. and foreign governments. An FDA sponsored survey of innovative medical

device companies found that nearly 65 percent of them sold their products outside the United States, including 40 percent of the small and 70 percent of the medium-sized companies.[3] Thus, a majority of firms should benefit from harmonization efforts. Since foreign firms exporting their products to the United States must comply with the U.S. CGMP regulation, they will incur essentially the same incremental costs to comply with the final CGMP regulation as domestic establishments.

3. Small Business Concerns

Some comments representing small businesses were concerned about the increase in procedural and documentation requirements. The procedures and paperwork requirements will be simpler for small medical device establishments relative to larger firms. Further, small businesses can reduce compliance costs by using FDA guidance and training materials, industry-generated guidance, and other technical assistance that is available. FDA is preparing an extensive range of technical support regarding the final CGMP regulation, including guidance documents, workshops, and other materials and presentations.

Several small businesses argued that the regulatory costs fall disproportionately on small business, hindering industry growth. The regulatory requirements apply equally to whoever is designing and developing new devices. However, the vast majority of firms are small and medium in size and these firms are least likely to have such design control procedures already in place. As a result, their incremental costs may be higher. Nevertheless, because procedures reflect the complexity of the processes they guide, small and medium-sized establishments should incur proportionately lower gross compliance costs for those activities than larger establishments.

4. Section 820.22 Quality audit

Some comments believed that requiring quality audits to be performed by individuals without direct responsibility for the matters being audited poses a severe burden for small business. This requirement is already present in the original CGMP regulation and thus was not addressed in the economic analysis of the final regulation.

5. Section 820.25 Personnel

Comments stated that the requirement to maintain files on consultants was onerous and interfered with manufacturers' selection processes. FDA modified this requirement and moved it to § 820.50 *Purchasing,* in the final CGMP regulation. Companies will now be required to verify that consultants meet specified requirements and define the type and extent of control they will exercise over them. The incremental compliance costs were judged to be negligible.

6. Section 820.30 Design control

Comments believed that the requirement stipulating that devices be sampled from three production runs before a device is released for routine distribution was too prescriptive and burdensome. FDA has modified the requirement in the final rule to require design validation of initial production units, lots, or batches, or their equivalent. This modification should give manufacturers greater flexibility in implementing this requirement.

Some comments from small businesses were critical of the requirement that independent personnel perform design reviews and stated that they will have to hire outside engineers for this task. In the final rule FDA allows greater flexibility and states that the independent personnel can be individual(s) who do not have direct responsibility for the design stage being reviewed. Thus, staff personnel (including engineers working on other components of the device and nonengineering personnel) can perform design reviews.

7. Section 820.40 Document control

Some comments believed that the cost of implementing documentation systems and other paperwork was understated. However, ERG's estimates included the incremental compliance costs for formalizing a written document control procedure and ERG considered paperwork requirements in its estimation. The final rule also extends document control requirements to the design phase and cost estimates for these requirements were added to the economic assessment.

Most companies consider document control procedures to be essential and have realized some benefits from such procedures, typically in the form of efficiency gains and avoided documentation mixups. These potential benefits were not quantified.

8. Section 820.50 Purchasing control

Comments questioned the need to establish the quality of materials purchased from long-established suppliers or from new suppliers of small quantities of components. Historical records, however, even for suppliers of small quantities, can be used to assess a supplier's quality. Supplier audits are not mandated in the CGMP regulation, but may be a useful tool in assessing a supplier's capabilities. Cost estimates for auditing from one- half to four new suppliers per year for small to very large establishments were included in the economic assessment.

9. Section 820.80 Receiving, in-process, and finished device acceptance

One comment believed that requiring manufacturers to retain the quantitative results of testing was excessive. The final rule stipulates that ''the results'' of acceptance activities are to be recorded, but does not specify that all quantitative results must be recorded. Because this requirement is consistent with current industry practices, incremental costs were not assigned to this section.

10. Section 820.90 Nonconforming product

Comments noted that identifying a product as ''reprocessed'' has a negative impact on sales. (FDA now uses the term ''reworked''.) This language was revised in the final rule to clarify that reworked devices need to be identified as such at the manufacturing facility to avoid mixups. No costs were estimated for this requirement.

D. Industry Costs

ERG estimated the total annual incremental cost of the final rule at $81.9 million. This includes $9.5 million in one-time costs that were annualized over 5 years at a 10 percent discount rate. Table 2 lists the most costly of the new requirements.

Costs were based on the incremental tasks each manufacturer must perform to achieve compliance. ERG retained most of the methodology and data from the proposed rule to estimate the costs of the final rule. Where applicable, costs were estimated for additional or changed final requirements. Also, the distribution of costs across establishment size was modified to reflect new information on the rate of product innovation.[4] The rates of innovation per year used for this analysis are: 0.4 percent for small, 1.3 percent for medium-sized, 2.6 percent for large, and 6.5 percent for very large establishments.

[3] ERG (1994). *FDA Survey of Establishments Introducing New Medical Devices.* (Task Order 3, Contract No. 223–91–8100.)

[4] ERG (1994). *FDA Survey of Establishments Introducing New Medical Devices.* (Task Order 3, Contract No. 223–91–8100).

TABLE 2.—TOTAL COMPLIANCE COSTS, BY MOST COSTLY INCREMENTAL TASKS

[$ millions]

Incremental tasks	One-time annualized [1]	Annual		Total annualized
		Labor	Nonlabor	
Design Controls:				
Design Verification	NA	18.2	27.4	45.6
Design Review	NA	6.2	NA	6.2
Design Changes	NA	4.0	NA	4.0
Design and Development Planning	NA	1.2	NA	1.2
Other:				
Quality Audit	0.5	4.7	NA	5.2
Evaluation of Suppliers and Contractors	0.6	1.9	0.9	3.4
Management Review	NA	2.2	NA	2.2
Purchasing Data	NA	1.1	NA	1.1
All Remaining	8.4	4.6	0.0	13.0
Total for Final Regulation	9.5	44.1	28.3	81.9

[1] One-time costs annualized over 5 years at discount rate of 10 percent.
NA=Not Applicable.
Note: Totals may not add due to rounding.
Source: ERG (1996), Section 4.

The great majority of costs for all size establishments will be associated with the establishment of design controls for new products. Therefore, the more innovative establishments will experience greater compliance costs than the less innovative establishments. The estimated annual design control costs total $57.5 million, which represents 70 percent of the total annual incremental costs of compliance. The most costly task within the design control category is design verification ($45.6 million), which includes design validation. Other costly tasks are design review ($6.2 million), which encompasses conducting and documenting design reviews; design changes ($4.0 million), which includes documenting and maintaining design change procedures; and design and development planning ($1.2 million), which includes documenting and maintaining plans for device design and development. The requirement for extending the quality system audit ($5.2 million) and the evaluation of suppliers and contractors ($3.4 million) are also relatively high cost items.

The estimated total cost of compliance for the final rule ($81.9 million) is $2.6 million less than the estimated cost of the November 1993 proposed rule ($84.5 million). Some cost increases were due to added requirements for increased documentation. However, these cost increases were offset partly by a decrease of $0.5 million from the modification of some requirements (e.g. §§ 820.65 *Traceability* and 820.160 *Distribution*). The remaining changes resulted from changes in assumptions or new information about cost and compliance rates in design control and supplier audits and from new information regarding product innovation rates across establishment size.

The projected average cost per establishment (see Table 3) varies substantially across industry sectors and establishment size categories. As expected, the average incremental costs are largest for establishments that design medical devices: design and production manufacturers and specification developers. For these two sectors, the average per establishment costs are $15,994 for design and production manufacturers and $14,767 for specification developers. Actual per establishment costs will vary substantially depending on the product type, design complexity, innovation rate, and level of design control currently in place. The average incremental costs for the other three sectors are significantly lower: $3,554 for contract manufacturer, $1,995 for repacker/relabeler, and $2,040 for contract sterilizer.

TABLE 3.—AVERAGE TOTAL ANNUALIZED [1] COSTS PER ESTABLISHMENT BY TYPE AND SIZE

[Dollars]

Establishment type	Small (1–19)	Medium (20–99)	Large (100–249)	Very large (≥250)	All
Design and Production Manufacturer	11,085	25,800	22,748	12,258	15,994
Specification Developer	9,927	24,052	20,583	NA	14,767
Contract Manufacturer	2,357	4,027	5,802	10,678	3,554
Repacker/Relabeler	1,471	2,588	3,969	NA	1,995
Contract Sterilizer	1,491	2,621	3,999	NA	2,400

[1] One-time costs annualized over 5 years at a discount rate of 10 percent.
NA=Not Applicable.
Source: ERG (1996), Section 6.

Because average current compliance rates tend to vary directly with establishment size and there are relatively few large and very large establishments (7 and 4 percent of all medical device establishments, respectively), the largest share of the costs are incurred by small establishments, $35.2 million (43

percent) and medium-size establishments, $34.5 million (42 percent), while the smallest share is incurred by very large establishments, $3.4 million (4 percent) (see Table 4).

TABLE 4.—TOTAL ANNUALIZED COSTS BY SIZE CATEGORY

[$ millions]

Establishment size	One-time annualized [1]	Annual		Total annualized
		Labor	Nonlabor	
Small (1–19)	4.9	18.2	12.1	35.2
Medium (20–99)	3.0	18.2	13.3	34.5
Large (100–249)	1.0	5.1	2.8	8.8
Very large (≥250)	0.7	2.6	0.1	3.4
All establishments	9.5	44.1	28.3	81.9

[1] One-time costs annualized over five years at discount rate of 10 percent.
Note: Totals may not add due to rounding.
Source: ERG (1996), Section 4.

E. Benefits From Proposed Changes to the CGMP Regulation

ERG used the methodology and data from the proposed rule to estimate the benefits of the final CGMP regulation. Adjustments to the number and distribution of MDR's were made based on updated numbers of closed cases. Also, more reliable estimates of industry savings from avoided design-related recalls were incorporated.

The changes to the CGMP regulation will provide public health benefits to medical device users and economic benefits to the medical device industry. Based on its review of medical device recalls over the 4-year period 1988 to 1991, FDA has estimated that 30 percent of all medical device product recalls are due to inadequate design controls. It is extremely difficult to judge how many of these recalls could reasonably have been avoided, but ERG judged that a majority would have been prevented if manufacturers had fully implemented the CGMP design control requirements.

1. Public Health Benefits

ERG used the MDR database to estimate the public health benefits of the final CGMP regulation. There were over 41,600 MDR's submitted to FDA in 1991; 97 percent of these MDR's are closed (i.e., a review of the case is completed). Of these closed cases, FDA determined that 9.3 percent of the fatalities and 12.4 percent of the serious injuries were due to device failures. The bulk of the remaining incidents were due to user problems, but also include cases where cause could not be clearly established. To estimate the total number of deaths and serious injuries for 1991 by cause, the 1988–1991 averages of device recalls were used. To estimate the number of deaths and serious injuries due to design-related causes, ERG assumed that the percent of MDR's that were design-related was the same as that for recalls (30 percent).[5] Based on these assumptions, medical devices contributed to an estimated 49 fatalities and 663 serious injuries in 1991 due to design-related problems in class II and III devices (see Table 5). To correct for the substantial under reporting of MDR's, ERG made an upward adjustment in the number of MDR's of 20 percent for fatalities and 40 percent for serious injuries. The number of estimated fatalities adjusted for underreporting of MDR's would be 59, with 929 serious injuries.

TABLE 5.—NUMBER OF DESIGN-RELATED REPORTS AND ESTIMATED AVOIDED DEATHS AND SERIOUS INJURIES

	Fatalities			Serious Injuries		
	Class II	Class III	Total	Class II	Class III	Total
Number in 1991	555	475	1,030	4,391	11,794	16,185
Device-related	105	59	164	330	1,881	2,211
Design-related [1]	32	18	49	99	564	663
Number avoided	23	13	36	72	412	484
Adjusted number of design-related MDR's [2]	38	21	59	139	790	929
Adjusted Number avoided	28	15	43	101	576	677

[1] Assumes 30 percent of device-related MDR's are design-related, based on FDA recall data.
[2] Total number of fatalities and injuries increased by 20 and 40 percent, respectively, to adjust for under-reporting.
Source: ERG (1996), Section 5.

To develop an approximate idea of the preventability of these incidents, ERG convened a panel of industrial engineers and regulatory specialists with extensive experience in the design of medical devices. The panel examined a random sample of 100 design-related medical device recalls and judged whether implementation of design controls could have prevented the recall. ERG found that the expected value of their judgments implied that proper design controls would have prevented about 73 percent of these recalls. Assuming the same preventability ratio for design-related MDR events, ERG calculated that the proposal would prevent about 36 to 43 deaths and 484 to 677 serious injuries per year, depending on the degree of MDR underreporting.

To verify the reasonableness of the estimates, FDA examined an alternative method of estimating the number of

[5] There is no code in the MDR database to identify design-related events.

fatalities caused by design-related failures. For this calculation, 3 years of design-related recalls were assumed linked to MDR fatalities that occurred for these devices 1 year before or 3 months after the date of the recall. This approach, which provides a conservative estimate because not all relevant fatalities and subsequent MDR's would occur during this limited time period, found that about 60 deaths per year were due to design-related device failures. If 73 percent of such incidents could be avoided through compliance with the proposed CGMP regulation, 44 deaths per year would be prevented.

These estimates of the public health benefits from fewer design-related deaths and serious injuries represent FDA's best projections, given the limitations and uncertainties of the data and assumptions. The above numbers, however, do not capture the quality of life losses to patients who experience less severe injuries than those reported in MDR's, who experience anxiety as a result of treatment with an unreliable medical device, or who experience inconvenience and additional medical costs because of device failure.

Medical device malfunctions are substantially more numerous than deaths or injuries from device failures and also represent a cost to society. Malfunctions represent a loss of product and an inconvenience to users and/or patients. Additionally, medical device malfunctions burden medical personnel with additional tasks, such as repeating treatments, replacing devices, returning and seeking reimbursement for failed devices, and providing reports on the circumstances of medical device failures. No attempt was made to quantify these additional costs.

2. Industry Benefits

The medical device industry would gain substantial economic benefits from the proposed changes to the CGMP regulation in three ways: Cost savings from fewer recalls, productivity gains from improved designs, and efficiency gains for export-oriented manufacturers who would now need to comply with only one set of quality standards.

An average of 359 medical device recall events per year were reported to FDA over the period 1988 to 1991. As stated above, FDA estimates that design-related deficiencies contributed to 30 percent of those recall events annually. Applying the 73 percent recall preventability factor, ERG projects that there would be 67 fewer recalls of class II and III devices each year under the final CGMP regulation (see Table 6). Based on data from a recent survey of recall costs, 67 fewer recalls implies that the industry would avoid roughly $29 million worth of recall expenses per year by complying with the final CGMP regulation.[6]

TABLE 6.—NUMBER OF AVOIDED DESIGN-RELATED RECALL EVENTS BY CLASS OF DEVICE

[FY 1988–FY 1991]

Device class	Average number of design-related recall events[1]	Number of avoided design-related recall events[2]
I	15	NA
II	80	58
III	12	9
All Devices	107	67

[1] Office of Compliance and Surveillance, CDRH.

[2] ERG estimates based on random sample of 100 design-related recalls.

Source: ERG (1996), Section 5.

ERG also found that the design control requirements in the final CGMP regulation would require manufacturers to integrate their design and production operations and that most industry experts believe that this change would lead to better quality products, more efficient engineering, lower manufacturing costs, and reduced product development time. These savings, however, could not be quantified.

Still another benefit of the revised regulation relates to the harmonization of the final CGMP regulation with the ISO 9001:1994 international standard. This change would especially benefit export-oriented establishments, because they would need to meet only one set of quality standards. ERG could not derive quantitative measures of this benefit. However, 65 percent of innovative medical device companies export their products, thus a majority should benefit from harmonization of CGMP regulation between major trading partners.[7]

F. Economic and Small Business Impact

The ability of medical device establishments to pass on the added cost of the final regulation will determine the economic impact to the industry. The diversity of medical devices precludes any easy characterization of their product markets. Under the current medical care system, however, the demand for many medical devices tends to be price inelastic because they are often prescribed by physicians and frequently paid for by third parties. Thus, small price increases have not typically prompted significant declines in industry sales. Nonetheless, competitive pressures have increased substantially under new health care cost-containment measures. Therefore, to examine the potential effect of the costs of compliance on the industry's competitive structure, ERG calculated the maximum impact on industry average prices and products, using extreme scenarios. Financial data characterizing the scope of FDA-regulated medical device establishments are not available. To make estimates of the regulatory impact on price and profits, ERG used a combination of census and Dun and Bradstreet data (see ERG (1993) for methodology). ERG assumed that the firms characterized in these data sources had the same size and product distribution, and introduced new products at the same rate as the population of FDA-regulated establishments. While the validity of these assumptions is uncertain, it was the only data available to measure regulatory impact. ERG presents two extreme scenarios, the first reflects the magnitude of the potential impact on product prices if all costs were passed forward. The second demonstrates the maximum drop in profits if no costs were passed forward. In reality, some combination of these scenarios will occur.

Based on the assumption that all costs of compliance are passed through to the end user, with no loss in sales and no offset for avoided recalls or other industry productivity gains, ERG found that the average increase in the price of medical devices would be less than 0.13 percent. Estimated price increases ranged from 0.04 percent for X-Ray Apparatus and Tubes (SIC 3844) to 0.34 percent for Dental Equipment and Supplies (SIC 3843) (see Table 7). The maximum price increase was calculated using aggregate compliance costs as a percentage of the value of shipments. The price increases calculated by size of establishment suggest that small establishments will be under greater pressure to increase prices. The cost of compliance represented an average of 1.36 percent of the value of shipments for small establishments and 0.01 percent for very large establishments. These differences in impacts by size reflect the finding that small

[6] Design-related medical device recalls cost the industry approximately $40 million annually. (Eastern Research Group, Inc. (1994). *FDA Survey of Medical Device Recall Costs.* (Task Order 3, Contract Number 223–91–8100).

[7] ERG (1994). *FDA Survey of Establishments Introducing New Medical Devices.* (Task Order 3, Contract No. 223–91–8100.)

establishments have lower current compliance than large establishments.

To estimate the potential impact of compliance costs on medical device industry profits, ERG calculated after-tax compliance costs as a percentage of after-tax income for each medical device SIC (see Table 7). Again, no adjustments were made for avoided recalls or expected productivity gains. If manufacturers have no ability to increase prices to offset the increase in compliance costs, this estimate represents an upper bound of the potential effect on entity income. Under these circumstances, the medical device sectors could incur reductions in income ranging from about 0.81 percent (SIC 3845, Electromedical Equipment) to about 4.27 percent (SIC 3843, Dental Equipment and Supplies). ERG concluded that such impacts may affect some establishments' decisions to develop new products where expected profits are marginal or highly uncertain, but judged that the level of incremental costs imposed by this regulation would not substantially lower the innovation rate especially for products with significant medical benefits.

TABLE 7.—MAXIMUM POTENTIAL IMPACT ON PRICE OR PROFITS BY INDUSTRY AND EMPLOYMENT SIZE

	Total annualized compliance costs as a percentage of shipments	After-tax compliance costs as a percentage of after-tax income
Industry:		
3841 Surgical and medical instruments	0.12	2.00
3842 Surgical appliance and supplies	0.14	1.78
3843 Dental equipment and supplies	0.34	4.27
3844 x-ray apparatus and tubes	0.04	0.88
3845 Electromedical equipment	0.05	0.81
3851 Ophthalmic goods	0.24	3.54
All	0.13	1.87
Establishment size:		
Small (1–19)	1.36	NA
Medium (20–99)	0.35	NA
Large (100–249)	0.09	NA
Very large (≥250)	0.01	NA
All	0.13	NA

NA = not available.
Source: ERG (1996), Section 6.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This section together with other discussions in this preamble and supporting analysis and materials constitute the agency's regulatory flexibility analysis. A description of the projected reporting, recordkeeping, and compliance requirements including the type of professional skills required is included in the ERG economic analysis reports that are referenced above and on file at the Dockets Management Branch (address above). In accordance with the Regulatory Flexibility Act, FDA has considered the effect of this action on small businesses and has determined that there will be a significant impact on a substantial number of small businesses. Almost all medical device establishments are classified as small under the Small Business Administrations definition of size.[8] The incremental costs are greatest for establishments that design medical devices and that currently have lower levels of compliance with the new design control requirements. These requirements account for 70 percent of the total incremental costs of the final rule but affect only design and production manufacturers and specification developers (82 percent of the total affected establishments). Other sectors of the industry will incur substantially lower costs (see Table 3).

The actual added cost per establishment will vary by the establishment's current level of compliance, complexity of product design, product type, and rate of product innovation. As indicated in Table 3, the average medium-size and large manufacturers of devices will incur greater compliance costs ($25,800 and $22,748 per establishment, respectively) relative to small and very large establishments ($11,085 and $12,258, respectively). However, the potential impact on product price (measured as a percent of the value of shipments) is greatest for small (1.36 percent) and medium-size (0.35 percent) establishments. Large and very large establishments will incur only a 0.09 percent and 0.01 percent increase, respectively, due to much larger values of shipments and higher rates of compliance with the final rule. Smaller establishments producing differentiated products or marketing to niche markets may not be at a disadvantage because of their ability to pass on the added cost of compliance. However, those smaller establishments that compete with larger establishments based on price alone would suffer a drop in profits if they currently operate at lower levels of compliance than their competitors.

FDA believes that actual per establishment compliance costs will be lower than estimated for the following reasons: First, the final CGMP regulation closely parallels the ISO 9001:1994 quality standards, which have been adopted as the quality standard for the EU and are becoming the international quality standards for medical devices. Close to 65 percent of domestic medical device manufacturers export their products and generate approximately one-third of their sales from exports.[9] Compliance with the quality control requirements is necessary for firms to maintain international competitiveness and in fact many U.S. medical device manufacturers have become ISO certified since the 1993 publication of the proposed CGMP regulation and the EU implementation of unified regulatory requirements.

Second, the FDA has extended the effective date of the final rule to June 1, 1997, and has chosen not to take regulatory action for an additional year on the design control requirements. This revised effective date will also reduce the cost of implementation estimated for the 1993 proposal where the proposed effective date was only 180 days after date of publication. The extension will give manufacturers a longer time to implement the new requirements, allowing the costs to be spread over almost a 2-year period as compared to 180 days. June 1998 coincides with the implementation of the EU's Inactive Medical Device Directive. Therefore, the economic impact of complying with the new quality system regulation will be shared with the economic impact of complying with the new EU Medical Device Directive for any manufacturer who also produces devices for sale in the EU, lessening the direct impact of the new quality system regulation.

Third, ERG estimates of the number of labor hours needed for design controls assume that many establishments have little or no formal system in place. Once an establishment has developed a system, minor modifications to an establishment's existing product (for which many 510(k) applications and PMA supplements are submitted) may be less costly than ERG assumed.

[8] The Small Business Administrations definition is by the employment size at the company level. Detailed demographic and financial data is not available by company size, therefore FDA used establishment data. FDA does not know the impact on companies.

[9] ERG (1994). *FDA Survey of Establishments Introducing New Medical Devices.* (Task Order 3, Contract No. 223–91–8100.)

Finally, cost estimates assume that establishments will use in-house expertise or hired consultants for all compliance activities. In fact, FDA and trade publications have disseminated much of the information that would be needed by the firms. FDA has taken many steps specifically to assist small businesses in complying with this final rule. The two stage implementation of the regulation was a concerted effort to reduce the regulatory burden on small businesses. Stage 1 was set up to be a 1 year training and cooperative phase for the entire medical device community. FDA and industry would be participating in a number of cooperative efforts as well as joint training exercises. Most importantly, FDA would be evaluating design controls and providing industry with feedback in the nature of a report. During this time, to truly allow it to be a learning experience for both the device manufacturers and the FDA investigators, there would be no regulatory actions taken as a result of these evaluations and reports. The biggest benefactor of the two stage implementation would clearly be small businesses.

Further, several guidances have been prepared by FDA for this regulation as a whole, as well as on subject matters that are significant in this final rule. FDA plans to release the following three guidances within 60 days after the final rule is published: (1) DSMA's ''Medical Device Quality Systems Manual: A Small Entity Compliance Guide,'' which includes discussion on the entire regulation plus multiple examples of procedures and forms that can be adopted and modified by manufacturers; (2) ''Design Control Guidance For Medical Device Manufacturers,'' which is intended to assist manufacturers in understanding the intent of the design control requirements. Assistance is provided by interpreting the language of the regulation and explaining the underlying concepts in practical terms; and (3) ''Do It By Design: An Introduction to Human Factors in Medical Devices,'' which contains background information about human factors as a discipline, descriptions and illustrations of device problems, and a discussion of human factors principles and methods as a part of the design control system. FDA also plans to release the following guidances after publication of this final rule: (1) A guidance on ''Validation,'' which will include discussions on design validation, computer validation, and process validation; and (2) a draft of the ''Design Control Inspectional Strategy,'' which will be the questions that FDA investigators will be asking when assuring compliance with the design control requirements.

FDA is also prepared to release shortly after publication of this final rule a 4 hour series of videotapes discussing the Quality System Regulation. The videotapes will also be accompanied by a guidebook entitled ''The FDA and World Wide Quality System Requirements Guidebook For Medical Devices.'' This guidebook will contain the entire Quality System Regulation from FDA, the entire text of ISO 9001:1994, FDA guidance from the regulation's preamble, and guidance on quality systems from the GHTF.

FDA has also tentatively scheduled two teleconferences. The first teleconference, which would be to discuss the Quality System Regulation and answer questions that have come up from manufacturers beginning to implement the regulation, is tentatively scheduled for December 1996. A second teleconference is tentatively scheduled for April/May of 1997 and will specifically address design controls and the final Design Control Inspectional Strategy. FDA is also exploring the possibility of conducting regional workshops in May of 1997 to further discuss the design control requirements and their implementation.

In addition to these activities, FDA and DSMA will continue to provide guidance and workshops that can help small business with their compliance activities, and will continue to participate in industry association workshops, conferences, and meetings. While all of the above-mentioned activities will be available to all manufacturers, small manufacturers will benefit the most from these FDA activities without having to pay substantial costs, as most of the guidance and written material will be available on the world wide web, and the teleconferences and other workshops sponsored or cosponsored by FDA will be of nominal cost.

Finally, as described elsewhere in this preamble, FDA intends to conduct a midcourse review of the new design control requirements during the transition year (June 1997 to June 1998). Specifically, the results of the first several months of design control inspections will be reviewed by early 1998, and any midcourse adjustments to the inspectional strategy will be instituted and made public by the Spring of 1998. Also during this midcourse review FDA will evaluate the information gathered at that point and determine if the design control requirements as written in this final rule are appropriate to obtain the goals expressed in this preamble. Any necessary adjustments or proposed revisions will be published in the Federal Register and comments will be solicited as necessary during the spring of 1998. This implementation strategy is responsive to requests by industry for FDA to harmonize the quality system regulation's implementation with the mandatory date for implementation of the EU's Medical Device Directive, which is June 1998. However, if during the midcourse review of stage one it is determined that the industry and/or FDA needs more time to fully implement the design control requirements, FDA will publish that decision in the Spring of 1998 prior to the June 1, 1998, regulatory implementation date.

Small businesses will also benefit in that FDA considered but rejected applying design requirements to all class I devices, because the added benefits to public health were not great enough to offset the increased burden on industry. Two requirements were eliminated or modified in the final rule that decreased the burden on industry: The applicability of the CGMP regulation to component suppliers was removed, and § 820.65 *Traceability* was limited to traceability of components where necessary to assure the protection of public health. These changes will particularly aid small businesses. In addition, revisions were made to many requirements in the final rule to make it less prescriptive and to allow establishments greater flexibility in implementing the requirements. Cost savings from these changes were not estimated.

In addition, revisions were made to many requirements in the final rule to make it less comprehensive in scope, less prescriptive and to allow establishments greater flexibility in implementing the requirements. Cost savings from these changes were not estimated. Based on the above, the agency has determined that the current rule represents the least burdensome alternative that meets the public health goal of reducing deaths and serious injuries attributable to defective medical devices.

In summary, FDA concludes that the estimated $81.9 million annual incremental cost to comply with the final CGMP regulation is likely an upward bound figure and that it would be substantially offset by significant savings from avoided recalls and more importantly, the avoidance of deaths and serious injuries due to design-related device failures. FDA's estimate of public health benefits includes the

prevention of 36 to 44 deaths and 484 to 677 serious injuries annually. Establishing design controls will also result in better designed and higher quality devices and fewer device failures. This quality improvement will in turn reduce the inconvenience and expense of repetitive treatments or diagnoses. The agency also believes the actual cost to comply with the final rule will be lower than estimated because the industry compliance baselines used to estimate costs are from 1993. Since that time, market pressures have induced many firms that export to the EU to become ISO 9001:1994 certified. These firms would now be in compliance with most of FDA's final CGMP regulation. Further, FDA has provided continued education efforts over the past 15 years, to mitigate industry costs.

IX. Paperwork Reduction Act of 1995

This final rule contains information collections that are subject to review by OMB under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The title, description and respondents of the information collection are shown below with an estimate of the annual incremental increase in the recordkeeping burden that respondents must undertake to achieve compliance with the final regulation.

Title: Medical Devices, Quality System Regulations, Current Good Manufacturing Practice Requirements.

Description: This final quality system regulation amends and revises the current good manufacturing practice requirements for medical devices, set out at 21 CFR part 820. This final regulation replaces quality assurance program requirements with quality system requirements; adds design and purchasing controls; modifies the critical device requirements; revises certain existing requirements, such as validation and management responsibility, to clarify the intent of the requirements; and harmonizes the CGMP regulations for medical devices with quality system specifications in ISO 9001:1994 ''Quality Systems-Model for Quality Assurance in Design, Development, Production, Installation and Servicing.''

Description of Respondents: Business or other for-profit and small businesses or organizations.

CFR section	Number of record-keepers	Annual frequency of recordkeeping	Total annual records	Hours per record-keeper	Total hours	Total operating and maintenance costs
820.20(a)	7,237	1	7,237	10.96	79,386	
820.20(b)	7,237	1	7,237	4.88	35,285	
820.20(c)	7,237	1	7,237	10.28	74,364	
820.20(d)	7,237	1	7,237	16.49	119,305	
820.20(e)	7,237	1	7,237	16.49	119,305	
820.22(a)	7,237	1	7,237	52.03	376,507	
820.25(b)	7,237	1	7,237	21.13	152,896	
820.30(a)(1)	7,237	1	7,237	2.92	21,162	
820.30(b)	7,237	1	7,237	9.91	71,718	
820.30(c)	7,237	1	7,237	2.92	21,162	
820.30(d)	7,237	1	7,237	2.92	21,162	
820.30(e)	7,237	1	7,237	38.98	282,115	
820.30(f)	7,237	1	7,237	62.37	451,342	$27,359,420
820.30(g)	7,237	1	7,237	62.37	451,342	
820.30(h)	7,237	1	7,237	5.56	40,236	
820.30(i)	7,237	1	7,237	28.77	208,173	
820.30(j)	7,237	1	7,237	4.40	31,848	
820.40	7,237	1	7,237	11.76	85,081	
820.40(b)	7,237	1	7,237			
820.50 (a)(1) to (a)(3)	7,237	1	7,237	31.12	225,240	898,500
820.50(b)	7,237	1	7,237	10.04	72,679	
820.60	7,237	1	7,237	0.54	3,914	
820.65	7,237	1	7,237			
820.70 (a)(1) to (a)(5)	7,237	1	7,237			
820.70 (b)–(c)	7,237	1	7,237			
820.70(d)	7,237	1	7,237	3.09	22,335	
820.70(e)	7,237	1	7,237			
820.70 (g)(1) to (g)(3)	7,237	1	7,237			
820.70(h)	7,237	1	7,237			
820.70(i)	7,237	1	7,237	9.41	68,092	
829.72(a)	7,237	1	7,237	5.83	42,165	
820.72 (b)(1) to (b)(3)	7,237	1	7,237			
820.75(a)	7,237	1	7,23	72.79	20,172	
820.75(b)	7,237	1	7,237			
820.75(b)(2)	7,237	1	7,237	0.15	1,096	
820.75(c)	7,237	1	7,237	0.15	1,096	
820.80 (a)–(e)	7,237	1	7,237			
820.86	7,237	1	7,237			
820.90(a)	7,237	1	7,237	6.11	44,217	
820.90 (b)(1) to (b)(2)	7,237	1	7,237	6.11	44,217	
820.100 (a)(1) to (a)(7)	7,237	1	7,237	20.06	145,144	
820.100(b)	7,237	1	7,237			
820.120	7,237	1	7,237			
820.120(b)	7,237	1	7,237			
820.120(d)	7,237	1	7,237			
820.130	7,237	1	7,237			
820.140	7,237	1	7,237	9.45	68,418	
820.150 (a)–(b)	7,237	1	7,237	9.45	68,418	
820.160 (a)–(b)	7,237	1	7,237			

CFR section	Number of record-keepers	Annual frequency of recordkeeping	Total annual records	Hours per record-keeper	Total hours	Total operating and maintenance costs
820.170 (a)–(b)	7,237	1	7,237			
820.180	7,237	1	7,237			
820.181 (a)–(e)	7,237	1	7,237			
820.184 (a)–(f)	7,237	1	7,237			
820.186	7,237	1	7,237			
820.198 (a)–(c)	7,237	1	7,237	3.71	26,850	
820.200(a) and 820.200(d)	7,237	1	7,237	4.35	31,459	
820.250	7,237	1	7,237			
Totals	7,237	1	7,237	487.50	3,527,901	28,257,920

[1] Incremental increase in hours and costs to achieve compliance with additional requirements.
Note: Totals may not add due to rounding

Under OMB information collection 0910–0073, which expired on June 30, 1995, there were 375,266 burden hours approved for recordkeeping requirements currently contained in part 820 to include 114,882 burden hours as a one time start up expenditure for 750 new firms. The additional requirements contained in this final rule will add 3,527,901 burden hours to the burden, resulting in a total annual recordkeeping burden of 3,903,167 hours. The 3,527,901 burden hours includes 1,433,579 burden hours for a one time start up expenditure for 7,237 manufacturers and 2,094,321 burden hours expended annually by 7,237 manufacturers.

The final rule estimate of recordkeeping burden includes about 9.6 times as many manufacturers with a one time start up expenditure, due to the addition of the design control requirements, than did FDA's estimate of the manufacturers that would have had a one time start up expenditure under the old regulation. Further the recordkeeping burden hour calculations for the new regulation were done under contract using a more complex methodology involving the estimated noncompliance ratio for small, medium, large, and very large manufacturers (as defined above) times the number of manufacturers in each category and factors in a rate of product innovation for new products, including 510(k) devices. This methodology is more precise than the methodology previously utilized. Therefore, it is very difficult to directly compare the total burden hours in this final rule as compared to the estimated burden hours filed for the old regulation which expired June 1995.

Approximately 85 percent of the additional burden hours for the final rule are from the following four subparts of part 820: (1) Subpart B—Quality System Requirements; (2) Subpart C—Design Controls; (3) Subpart E—Purchasing Controls; and (4) Subpart J—Corrective and Preventive Action. Over 45 percent of the 3,527,901 burden hours are attributed directly to the addition of design control requirements. The recordkeeping burden hours for design control are significant because of the nature of the new requirements, as well as in response to numerous comments on the 1993 and 1995 proposals. The comments requested that the regulation focus on procedures required under design control as compared to prescriptive requirements on the design activities. The quality system requirements, as well as the corrective and preventive action requirements combined are approximately 31 percent of the additional recordkeeping burden hours and were in response to two major issues: (1) Most importantly, FDA had identified these two areas as two of the top four deficiencies found during inspections of the medical device industry, across all sizes of manufacturers; and (2) numerous comments requested harmonization with the ISO 9000 series standards. The involvement of management with executive responsibility, the concept of a total quality system which is a closed feedback loop system, and the practice of using that closed loop system in taking appropriate corrective and preventive action is paramount in ensuring that safe and effective medical devices are available to the public. The purchasing control requirements and the respective recordkeeping burden are approximately 8 percent of the additional recordkeeping burden. Purchasing requirements were the overwhelming choice of the medical device industry as compared to the option of the final rule encompassing component manufacturers. See the discussion in section V.7. of this document.

It is important to note that small manufacturers may comply with this final rule with less procedures and paperwork than larger manufacturers of the same product because the structure and interfaces for a small manufacturer often require less documentation and paperwork.

Although the November 23, 1993, proposed rule provided a 90 day comment period under the Paperwork Reduction Act of 1980, and this final rule incorporates the comments received, as required by 44 U.S.C. section 3507(d), FDA is providing additional opportunities for public comment under the Paperwork Reduction Act of 1995, which applies to this final rule and was enacted after the expiration of the comment period.

Therefore, the agency solicits public comment on the information collection requirements in order to: (1) 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; (2) 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; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Individuals and organizations may submit comments on the information collection requirements by December 6, 1996, and should direct comments to FDA's Dockets Management Branch (address above).

Prior to the effective date of this final rule, FDA will publish a notice in the Federal Register when the information collection requirements in this rule are submitted for OMB approval, and again when OMB makes a decision to approve, modify, or disapprove the

information collection requirements. Persons are not required to respond to a collection of information unless it displays a currently valid OMB control number.

X. Congressional Review

This final rule has been determined to be a major rule for purposes of 5 U.S.C. 801 *et seq.*, Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121). FDA is submitting the information and reports as required by that statute.

XI. References

The following references have been placed on display in the Dockets Management Branch and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. ''Device Recalls: A Study of Quality Problems,'' FDA, Center for Devices and Radiological Health, Rockville, MD 20857, HHS Publication FDA 90–4235, January 1990.

2. ''FDA Medical Device Regulation From Premarket Review to Recall,'' Office of Inspector General, Washington, DC, HHS Publication OEI 09–90–00040, February 1991.

3. ''Software Related Recalls for Fiscal Years FY 83—FY 91,'' FDA, Center for Devices and Radiological Health, Rockville, MD 20857, May 1992.

4. ISO 9001:1994 ''Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing.''

5. ISO draft revision of ISO/CD 13485 ''Quality Systems—Medical Devices—Supplementary Requirements to ISO 9001.''

6. Federal Register notice entitled ''Medical Devices; Current Good Manufacturing Practices (CGMP) Regulations Document; Suggested Changes; Availability,'' November 30, 1990 (55 FR 49644).

7. Federal Register notice entitled ''Medical Devices; Current Good Manufacturing Practice (CGMP) Regulations; Proposed Revisions; Request for Comments,'' November 23, 1993 (55 FR 61952).

8. Federal Register notice entitled ''Medical Devices; Working Draft of the Current Good Manufacturing Practice (CGMP) Final Rule; Notice of Availability; Request for Comments; Public Meeting,'' July 24, 1995 (60 FR 37856).

9. European Standard (EN) 46001 ''Quality Systems—Medical Devices—Particular Requirements for the Application of EN 29001.''

10. ''Guidelines on General Principles of Process Validation,'' Center for Drugs and Biologics, and Center for Devices and Radiological Health, FDA, Rockville, MD 20857, May 11, 1987.

11. ''Medical Devices; Early Warning of Problems Is Hampered by Severe Underreporting,'' United States General Accounting Office, Washington, DC, GAO/PEMD–87–1.

List of Subjects

21 CFR Part 808

Intergovernmental relations, Medical devices.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 820

Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 808, 812, and 820 are amended as follows:

PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

1. The authority citation for 21 CFR part 808 is revised to read as follows:

Authority: Secs. 520, 521, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j, 360k, 371).

2. Section 808.1 is amended by adding new paragraph (d)(10) to read as follows:

§ 808.1 Scope.

* * * * *

(d) * * *

(10) Part 820 of this chapter (21 CFR part 820) (CGMP requirements) does not preempt remedies created by States or Territories of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

* * * * *

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

3. The authority citation for 21 CFR part 812 is revised to read as follows:

Authority: Secs. 301, 501, 502, 503, 505, 506, 507, 510, 513–516, 518–520, 701, 702, 704, 721, 801, 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 353, 355, 356, 357, 360, 360c-360f, 360h-360j, 371, 372, 374, 379e, 381, 383); secs. 215, 301, 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263b-263n).

4. Section 812.1 *Scope* is amended by revising the fourth sentence of paragraph (a) to read as follows:

§ 812.1 Scope.

(a) * * * An IDE approved under § 812.30 or considered approved under § 812.2(b) exempts a device from the requirements of the following sections of the Federal Food, Drug, and Cosmetic Act (the act) and regulations issued thereunder: Misbranding under section 502 of the act, registration, listing, and premarket notification under section 510, performance standards under section 514, premarket approval under section 515, a banned device regulation under section 516, records and reports under section 519, restricted device requirements under section 520(e), good manufacturing practice requirements under section 520(f) except for the requirements found in § 820.30, if applicable (unless the sponsor states an intention to comply with these requirements under § 812.20(b)(3) or § 812.140(b)(4)(v)) and color additive requirements under section 721.

* * * * *

5. Part 820 is revised to read as follows:

PART 820—QUALITY SYSTEM REGULATION

Subpart A—General Provisions

Sec.
820.1 Scope.
820.3 Definitions.
820.5 Quality system.

Subpart B—Quality System Requirements

820.20 Management responsibility.
820.22 Quality audit.
820.25 Personnel.

Subpart C—Design Controls

820.30 Design controls.

Subpart D—Document Controls

820.40 Document controls.

Subpart E—Purchasing Controls

820.50 Purchasing controls.

Subpart F—Identification and Traceability

820.60 Identification.
820.65 Traceability.

Subpart G—Production and Process Controls

820.70 Production and process controls.
820.72 Inspection, measuring, and test equipment.
820.75 Process validation.

Subpart H—Acceptance Activities

820.80 Receiving, in-process, and finished device acceptance.
820.86 Acceptance status.

Subpart I—Nonconforming Product

820.90 Nonconforming product.

Subpart J—Corrective and Preventive Action

820.100 Corrective and preventive action.

Subpart K—Labeling and Packaging Control

820.120 Device labeling.
820.130 Device packaging.

Subpart L—Handling, Storage, Distribution, and Installation

820.140 Handling.
820.150 Storage.

820.160 Distribution.
820.170 Installation.

Subpart M—Records

820.180 General requirements.
820.181 Device master record.
820.184 Device history record.
820.186 Quality system record.
820.198 Complaint files.

Subpart N—Servicing

820.200 Servicing.

Subpart O—Statistical Techniques

820.250 Statistical techniques.

Authority: Secs. 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383).

Subpart A—General Provisions

§ 820.1 Scope.

(a) *Applicability.*

(1) Current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act). This part establishes basic requirements applicable to manufacturers of finished medical devices. If a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged. With respect to class I devices, design controls apply only to those devices listed in § 820.30(a)(2). This regulation does not apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidance. Manufacturers of human blood and blood components are not subject to this part, but are subject to part 606 of this chapter.

(2) The provisions of this part shall be applicable to any finished device as defined in this part, intended for human use, that is manufactured, imported, or offered for import in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(3) In this regulation the term ''where appropriate'' is used several times. When a requirement is qualified by ''where appropriate,'' it is deemed to be ''appropriate'' unless the manufacturer can document justification otherwise. A requirement is ''appropriate'' if nonimplementation could reasonably be expected to result in the product not meeting its specified requirements or the manufacturer not being able to carry out any necessary corrective action.

(b) *Limitations.* The quality system regulation in this part supplements regulations in other parts of this chapter except where explicitly stated otherwise. In the event that it is impossible to comply with all applicable regulations, both in this part and in other parts of this chapter, the regulations specifically applicable to the device in question shall supersede any other generally applicable requirements.

(c) *Authority.* Part 820 is established and issued under authority of sections 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, 803 of the act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383). The failure to comply with any applicable provision in this part renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.

(d) *Foreign manufacturers.* If a manufacturer who offers devices for import into the United States refuses to permit or allow the completion of a Food and Drug Administration (FDA) inspection of the foreign facility for the purpose of determining compliance with this part, it shall appear for purposes of section 801(a) of the act, that the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, or servicing of any devices produced at such facility that are offered for import into the United States do not conform to the requirements of section 520(f) of the act and this part and that the devices manufactured at that facility are adulterated under section 501(h) of the act.

(e) *Exemptions or variances.* (1) Any person who wishes to petition for an exemption or variance from any device quality system requirement is subject to the requirements of section 520(f)(2) of the act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in § 10.30 of this chapter, the FDA's administrative procedures. Guidance is available from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance, (HFZ–220), 1350 Piccard Dr., Rockville, MD 20850, U.S.A., telephone 1–800–638–2041 or 1–301–443–6597, FAX 301–443–8818.

(2) FDA may initiate and grant a variance from any device quality system requirement when the agency determines that such variance is in the best interest of the public health. Such variance will remain in effect only so long as there remains a public health need for the device and the device would not likely be made sufficiently available without the variance.

§ 820.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–903, 52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 321–394)). All definitions in section 201 of the act shall apply to the regulations in this part.

(b) *Complaint* means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

(c) *Component* means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.

(d) *Control number* means any distinctive symbols, such as a distinctive combination of letters or numbers, or both, from which the history of the manufacturing, packaging, labeling, and distribution of a unit, lot, or batch of finished devices can be determined.

(e) *Design history file (DHF)* means a compilation of records which describes the design history of a finished device.

(f) *Design input* means the physical and performance requirements of a device that are used as a basis for device design.

(g) *Design output* means the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.

(h) *Design review* means a documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.

(i) *Device history record (DHR)* means a compilation of records containing the production history of a finished device.

(j) *Device master record (DMR)* means a compilation of records containing the procedures and specifications for a finished device.

(k) *Establish* means define, document (in writing or electronically), and implement.

(l) *Finished device* means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

(m) *Lot or batch* means one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.

(n) *Management with executive responsibility* means those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and quality system.

(o) *Manufacturer* means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

(p) *Manufacturing material* means any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.

(q) *Nonconformity* means the nonfulfillment of a specified requirement.

(r) *Product* means components, manufacturing materials, in- process devices, finished devices, and returned devices.

(s) *Quality* means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.

(t) *Quality audit* means a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.

(u) *Quality policy* means the overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.

(v) *Quality system* means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

(w) *Remanufacturer* means any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.

(x) *Rework* means action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution.

(y) *Specification* means any requirement with which a product, process, service, or other activity must conform.

(z) *Validation* means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

(1) *Process validation* means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

(2) *Design validation* means establishing by objective evidence that device specifications conform with user needs and intended use(s).

(aa) *Verification* means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

§ 820.5 Quality system.

Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part.

Subpart B—Quality System Requirements

§ 820.20 Management responsibility.

(a) *Quality policy.* Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.

(b) *Organization.* Each manufacturer shall establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements of this part.

(1) *Responsibility and authority.* Each manufacturer shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks.

(2) *Resources.* Each manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this part.

(3) *Management representative.* Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for:

(i) Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and

(ii) Reporting on the performance of the quality system to management with executive responsibility for review.

(c) *Management review.* Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy and objectives. The dates and results of quality system reviews shall be documented.

(d) *Quality planning.* Each manufacturer shall establish a quality plan which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured. The manufacturer shall establish how the requirements for quality will be met.

(e) *Quality system procedures.* Each manufacturer shall establish quality system procedures and instructions. An outline of the structure of the documentation used in the quality system shall be established where appropriate.

§ 820.22 Quality audit.

Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a reaudit of deficient matters,

shall be taken when necessary. A report of the results of each quality audit, and reaudit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and reaudits shall be documented.

§ 820.25 Personnel.

(a) *General.* Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed.

(b) *Training.* Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented.

(1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.

(2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.

Subpart C—Design Controls

§ 820.30 Design controls.

(a) *General.* (1) Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

(2) The following class I devices are subject to design controls:

(i) Devices automated with computer software; and

(ii) The devices listed in the following chart.

Section	Device
868.6810	Catheter, Tracheobronchial Suction.
878.4460	Glove, Surgeon's.
880.6760	Restraint, Protective.
892.5650	System, Applicator, Radionuclide, Manual.
892.5740	Source, Radionuclide Teletherapy.

(b) *Design and development planning.* Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.

(c) *Design input.* Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

(d) *Design output.* Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented.

(e) *Design review.* Each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. The results of a design review, including identification of the design, the date, and the individual(s) performing the review, shall be documented in the design history file (the DHF).

(f) *Design verification.* Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF.

(g) *Design validation.* Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.

(h) *Design transfer.* Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

(i) *Design changes.* Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

(j) *Design history file.* Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.

Subpart D—Document Controls

§ 820.40 Document controls.

Each manufacturer shall establish and maintain procedures to control all documents that are required by this part. The procedures shall provide for the following:

(a) *Document approval and distribution.* Each manufacturer shall designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this part. The approval, including the date and signature of the individual(s) approving the document, shall be documented. Documents established to meet the requirements of this part shall be available at all locations for which they are designated, used, or otherwise necessary, and all obsolete documents shall be promptly removed from all points of use or otherwise prevented from unintended use.

(b) *Document changes.* Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise. Approved changes shall be

communicated to the appropriate personnel in a timely manner. Each manufacturer shall maintain records of changes to documents. Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective.

Subpart E—Purchasing Controls

§ 820.50 Purchasing controls.

Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

(a) *Evaluation of suppliers, contractors, and consultants.* Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants. Each manufacturer shall:

(1) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.

(2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.

(3) Establish and maintain records of acceptable suppliers, contractors, and consultants.

(b) *Purchasing data.* Each manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the quality of a finished device. Purchasing data shall be approved in accordance with § 820.40.

Subpart F—Identification and Traceability

§ 820.60 Identification.

Each manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mixups.

§ 820.65 Traceability.

Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.

Subpart G—Production and Process Controls

§ 820.70 Production and process controls.

(a) *General.* Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include:

(1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;

(2) Monitoring and control of process parameters and component and device characteristics during production;

(3) Compliance with specified reference standards or codes;

(4) The approval of processes and process equipment; and

(5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

(b) *Production and process changes.* Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to § 820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with § 820.40.

(c) *Environmental control.* Where environmental conditions could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures to adequately control these environmental conditions. Environmental control system(s) shall be periodically inspected to verify that the system, including necessary equipment, is adequate and functioning properly. These activities shall be documented and reviewed.

(d) *Personnel.* Each manufacturer shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and product or environment could reasonably be expected to have an adverse effect on product quality. The manufacturer shall ensure that maintenance and other personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised by a trained individual.

(e) *Contamination control.* Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

(f) *Buildings.* Buildings shall be of suitable design and contain sufficient space to perform necessary operations, prevent mixups, and assure orderly handling.

(g) *Equipment.* Each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.

(1) *Maintenance schedule.* Each manufacturer shall establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met. Maintenance activities, including the date and individual(s) performing the maintenance activities, shall be documented.

(2) *Inspection.* Each manufacturer shall conduct periodic inspections in accordance with established procedures to ensure adherence to applicable equipment maintenance schedules. The inspections, including the date and individual(s) conducting the inspections, shall be documented.

(3) *Adjustment.* Each manufacturer shall ensure that any inherent limitations or allowable tolerances are visibly posted on or near equipment requiring periodic adjustments or are readily available to personnel performing these adjustments.

(h) *Manufacturing material.* Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material

to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.

(i) *Automated processes.* When computers or automated data processing systems are used as part of production or the quality system, the manufacturer 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.

§ 820.72 Inspection, measuring, and test equipment.

(a) *Control of inspection, measuring, and test equipment.* Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained. These activities shall be documented.

(b) *Calibration.* Calibration procedures shall include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for remedial action to reestablish the limits and to evaluate whether there was any adverse effect on the device's quality. These activities shall be documented.

(1) *Calibration standards.* Calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards. If national or international standards are not practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.

(2) *Calibration records.* The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented. These records shall be displayed on or near each piece of equipment or shall be readily available to the personnel using such equipment and to the individuals responsible for calibrating the equipment.

§ 820.75 Process validation.

(a) Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be documented.

(b) Each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met.

(1) Each manufacturer shall ensure that validated processes are performed by qualified individual(s).

(2) For validated processes, the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process or the major equipment used shall be documented.

(c) When changes or process deviations occur, the manufacturer shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented.

Subpart H—Acceptance Activities

§ 820.80 Receiving, in-process, and finished device acceptance.

(a) *General.* Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities.

(b) *Receiving acceptance activities.* Each manufacturer shall establish and maintain procedures for acceptance of incoming product. Incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements. Acceptance or rejection shall be documented.

(c) *In-process acceptance activities.* Each manufacturer shall establish and maintain acceptance procedures, where appropriate, to ensure that specified requirements for 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 are documented.

(d) *Final acceptance activities.* Each manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria. Finished devices shall be held in quarantine or otherwise adequately controlled until released. Finished devices shall not be released for distribution until: (1) The activities required in the DMR are completed; (2) the associated data and documentation is reviewed; (3) the release is authorized by the signature of a designated individual(s); and (4) the authorization is dated.

(e) *Acceptance records.* Each manufacturer shall document acceptance activities required by this part. These records shall include: (1) The acceptance activities performed; (2) the dates acceptance activities are performed; (3) the results; (4) the signature of the individual(s) conducting the acceptance activities; and (5) where appropriate the equipment used. These records shall be part of the DHR.

§ 820.86 Acceptance status.

Each manufacturer shall identify by suitable means the acceptance status of product, to indicate the conformance or nonconformance of product with acceptance criteria. The identification of acceptance status shall be maintained throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used, or installed.

Subpart I—Nonconforming Product

§ 820.90 Nonconforming product.

(a) *Control of nonconforming product.* Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented.

(b) *Nonconformity review and disposition.* (1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.

(2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

Subpart J—Corrective and Preventive Action

§ 820.100 Corrective and preventive action.

(a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

(1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

(2) Investigating the cause of nonconformities relating to product, processes, and the quality system;

(3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

(4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;

(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

(6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

(b) All activities required under this section, and their results, shall be documented.

Subpart K—Labeling and Packaging Control

§ 820.120 Device labeling.

Each manufacturer shall establish and maintain procedures to control labeling activities.

(a) *Label integrity.* Labels shall be printed and applied so as to remain legible and affixed during the customary conditions of processing, storage, handling, distribution, and where appropriate use.

(b) *Labeling inspection.* Labeling shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct expiration date, control number, storage instructions, handling instructions, and any additional processing instructions. The release, including the date and signature of the individual(s) performing the examination, shall be documented in the DHR.

(c) *Labeling storage.* Each manufacturer shall store labeling in a manner that provides proper identification and is designed to prevent mixups.

(d) *Labeling operations.* Each manufacturer shall control labeling and packaging operations to prevent labeling mixups. The label and labeling used for each production unit, lot, or batch shall be documented in the DHR.

(e) *Control number.* Where a control number is required by § 820.65, that control number shall be on or shall accompany the device through distribution.

§ 820.130 Device packaging.

Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

Subpart L—Handling, Storage, Distribution, and Installation

§ 820.140 Handling.

Each manufacturer shall establish and maintain procedures to ensure that mixups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling.

§ 820.150 Storage.

(a) Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.

(b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

§ 820.160 Distribution.

(a) Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution. Where a device's fitness for use or quality deteriorates over time, the procedures shall ensure that expired devices or devices deteriorated beyond acceptable fitness for use are not distributed.

(b) Each manufacturer shall maintain distribution records which include or refer to the location of:

(1) The name and address of the initial consignee;

(2) The identification and quantity of devices shipped;

(3) The date shipped; and

(4) Any control number(s) used.

§ 820.170 Installation.

(a) Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device.

(b) The person installing the device shall ensure that the installation, inspection, and any required testing are performed in accordance with the manufacturer's instructions and procedures and shall document the inspection and any test results to demonstrate proper installation.

Subpart M—Records

§ 820.180 General requirements.

All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to

minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.

(a) *Confidentiality.* Records deemed confidential by the manufacturer may be marked to aid FDA in determining whether information may be disclosed under the public information regulation in part 20 of this chapter.

(b) *Record retention period.* All records required by this part shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer.

(c) *Exceptions.* This section does not apply to the reports required by § 820.20(c) Management review, § 820.22 Quality audits, and supplier audit reports used to meet the requirements of § 820.50(a) Evaluation of suppliers, contractors, and consultants, but does apply to procedures established under these provisions. Upon request of a designated employee of FDA, an employee in management with executive responsibility shall certify in writing that the management reviews and quality audits required under this part, and supplier audits where applicable, have been performed and documented, the dates on which they were performed, and that any required corrective action has been undertaken.

§ 820.181 Device master record.

Each manufacturer shall maintain device master records (DMR's). Each manufacturer shall ensure that each DMR is prepared and approved in accordance with § 820.40. The DMR for each type of device shall include, or refer to the location of, the following information:

(a) Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications;

(b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;

(c) Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used;

(d) Packaging and labeling specifications, including methods and processes used; and

(e) Installation, maintenance, and servicing procedures and methods.

§ 820.184 Device history record.

Each manufacturer shall maintain device history records (DHR's). Each manufacturer shall establish and maintain procedures to ensure that DHR's for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the DMR and the requirements of this part. The DHR shall include, or refer to the location of, the following information:

(a) The dates of manufacture;

(b) The quantity manufactured;

(c) The quantity released for distribution;

(d) The acceptance records which demonstrate the device is manufactured in accordance with the DMR;

(e) The primary identification label and labeling used for each production unit; and

(f) Any device identification(s) and control number(s) used.

§ 820.186 Quality system record.

Each manufacturer shall maintain a quality system record (QSR). The QSR shall include, or refer to the location of, procedures and the documentation of activities required by this part that are not specific to a particular type of device(s), including, but not limited to, the records required by § 820.20. Each manufacturer shall ensure that the QSR is prepared and approved in accordance with § 820.40.

§ 820.198 Complaint files.

(a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:

(1) All complaints are processed in a uniform and timely manner;

(2) Oral complaints are documented upon receipt; and

(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 or 804 of this chapter, Medical Device Reporting.

(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer 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.

(c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.

(d) Any complaint that represents an event which must be reported to FDA under part 803 or 804 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by § 820.198(e), records of investigation under this paragraph shall include a determination of:

(1) Whether the device failed to meet specifications;

(2) Whether the device was being used for treatment or diagnosis; and

(3) The relationship, if any, of the device to the reported incident or adverse event.

(e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:

(1) The name of the device;

(2) The date the complaint was received;

(3) Any device identification(s) and control number(s) used;

(4) The name, address, and phone number of the complainant;

(5) The nature and details of the complaint;

(6) The dates and results of the investigation;

(7) Any corrective action taken; and

(8) Any reply to the complainant.

(f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.

(g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:

(1) A location in the United States where the manufacturer's records are regularly kept; or

(2) The location of the initial distributor.

Subpart N—Servicing

§ 820.200 Servicing.

(a) Where servicing is a specified requirement, each manufacturer shall establish and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements.

(b) Each manufacturer shall analyze service reports with appropriate

statistical methodology in accordance with § 820.100.

(c) Each manufacturer who receives a service report that represents an event which must be reported to FDA under part 803 or 804 of this chapter shall automatically consider the report a complaint and shall process it in accordance with the requirements of § 820.198.

(d) Service reports shall be documented and shall include:

(1) The name of the device serviced;

(2) Any device identification(s) and control number(s) used;

(3) The date of service;

(4) The individual(s) servicing the device;

(5) The service performed; and

(6) The test and inspection data.

Subpart O—Statistical Techniques

§ 820.250 Statistical techniques.

(a) Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.

(b) Sampling plans, when used, shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.

Dated: October 1, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96–25720 Filed 10–3–96; 11:22 am]

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federal register

Monday
October 7, 1996

Part VIII

Department of Agriculture

Natural Resources Conservation Service
Farm Service Agency

7 CFR Chapters VI and VII

Implementation of the Conservation Provisions of the Federal Agriculture Improvement and Reform Act of 1996; Proposed Rule and Interim Rule

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

7 CFR Chapter VI

Farm Service Agency

7 CFR Chapter VII

AGENCY: Natural Resources Conservation Service and Farm Service Agency, USDA.

ACTION: Announcement of forums on proposed rules.

SUMMARY: The United States Department of Agriculture's, Natural Resources Conservation Service (NRCS) and Farm Service Agency (FSA) will conduct 54 public forums where interested individuals can provide comments and ideas on the implementation of the conservation provisions of the Federal Agriculture Improvement and Reform Act of 1996 (the 1996 Act), which includes: Highly Erodible Land Compliance, Wetlands Conservation, Conservation Reserve Program (CRP), and the Environmental Quality Incentives Program (EQIP).

DATES: Written or faxed comments are due on or before October 22, 1996.

See the Supplementary Information section for the dates of the forums.

ADDRESSES: Send comments to:

For comments pertaining to Highly Erodible Land Compliance, Wetland Conservation, and EQIP: Lloyd Wright, Director, Conservation and Ecosystem Assistance Division, USDA/NRCS, P. O. Box 2890, Washington, DC. 20250, FAX: 202–720–4265

For comments pertaining to CRP: Cheryl Zavodny, Conservation and Environmental Protection Division, USDA/FSA, P. O. Box 2415, Washington, D. C. 20250, FAX: 202–690–3433.

See the Supplementary Information Section for the location of the forums.

FOR FURTHER INFORMATION CONTACT:

Lloyd Wright, USDA/NRCS, Phone: 202–720–1845

Cheryl Zavodny, USDA/FSA, Phone: 202–720–7333.

See the Supplementary Information section for forum contacts for each State.

SUPPLEMENTARY INFORMATION: The public is invited to attend the meetings to provide brief oral comments. All are encouraged to provide detailed written comments concerning the implementation of the Act of 1996. Those who wish to speak at a meeting may make arrangements in advance by calling the state contact listed for the meeting. In addition, individuals wishing to provide oral presentations may sign-up at the forum, as time permits.

The forums will be held October 11–21 at the following locations on the dates listed:

Location	Date
Alabama Department of Agriculture and Industries, Richard Beard Building (Auditorium),1445 Federal Drive, Montgomery, AL	October 17.
Cooperative Extension, 1514 South Cushman Avenue, Room 303, Fairbanks, AK	October 18.
Mesa Pavilion Hilton, 1011 W. Holmes Avenue, Mesa, AZ (Superstition Freeway and Alma School Road)	October 15.
Arkansas Cooperative Extension Service Auditorium, 2301 South University Avenue, Little Rock, AR	October 11.
Holiday Inn Capitol Plaza, 300 J Street, Sacramento, CA	October 15.
Elks Lodge in Longmont, CO, Coffman Street, Longmont, CO	October 16.
Windsor Public Library, 323 Broad Street, Basement Level, Windsor, CT	October 16.
Delaware Department of Agriculture Conference Room, 2320 S. duPont Highway, Dover, DE	October 15.
Holiday Inn West (Bay Room), 7417 W. Newberry Road, Gainesville, FL	October 16.
Sunbelt Agricultural Exposition, West Exhibitors Lounge, Highway 133, Gate 3, Spence Field, Moultrie, GA	October 17.
USDA/NRCS Conference Room, FHB Building, Suite 301, 400 Rt 8, Maite, GU	October 18 (via Peace Satellite)
Pacific Beach Hotel, 2490 Kalakaua Avenue, Honolulu, HI	October 15.
Nampa Civic Center, 311 3rd Street South (North Banquet Room), Nampa, ID	October 16.
Illinois Department of Agricultural Auditorium, State Fairgrounds, 801 East Sangamon Avenue, Springfield, IL	October 15.
Indiana Farm Bureau Building, Meeting Room Assembly Hall D, 225 South East Street, Indianapolis, IN	October 18
Holiday Inn Downtown, 1050 6th Avenue, Des Moines, IA	October 18.
The Holidome, 1616 W. Crawford Street, Salina, KS	October 16.
NRCS State Office Conference Room, 771 Corporate Drive, Suite 110, Lexington, KY	October 17.
Ramada Inn Convention Centre, 2211 MacArthur Drive, Alexandria, LA	October 16.
Black Bear Inn, 4 Godfrey Drive, Orono, ME	October 17.
Chesapeake College, Kent Humanities Building, Room H117, US Route 50 and State Route 213, PO Box 8, Wye Mills, MD	October 15.
USDA/NRCS Conference Room, 451 West Street, Amherst, MA	October 15.
Ottawa Building, 611 West Ottawa Street, Conference Room 3, Upper Parking Level, Lansing, MI	October 15.
St. Cloud Civic Center, Stockinger Suite, 10 4th Avenue South, St. Cloud, MN	October 15.
Mississippi Agriculture and Forestry Museum, Ethnic Heritage Center, 1150 Lakeland Drive, Jackson, MS	October 15.
Holiday Inn Select, 2200 I–70 Drive S.W., Columbia, MO	October 15.
Eagles Lobby Conference Room, 24 North 8th, Miles City, MT	October 17.
Salvation Army Building Auditorium, 1000 17th Avenue South, Great Falls, MT	October 18.
I–80 Holiday Inn (Intersection of Highway 281 and I–80), Grand Island, NE	October 15.
Farm Service Agency State Office, 1755 E. Plumb Lane, Room 202, Reno, NV	October 17.
New Hampshire Department of Agriculture, Markets and Food, State House Annex Building, 2nd Floor, Room 201, Concord, NH	October 15.
Burlington County Board of Agriculture, 122 High Street, Mt. Holly, NJ	October 17.
USDA Conference Room, 6200 Jefferson NE, Albuquerque, NM	October 15.
Art & Home Center, New York State Fairgrounds, Syracuse, NY	October 15.
USDA/NRCS, 4405 Bland Road, Room 175, Raleigh, NC	October 18.
Hospitality Inn, 532 15th Street W, PO Box 1778, Dickinson, ND	October 15
Dakota Inn, Junction 281 S & 194, PO Box 1865, Jamestown, ND, (701) 252–3611	October 16
Holiday Inn (Formerly Sheraton Inn Riverside), 2200 Burdick Expressway East, PO Box 2228, Minot, ND	October 18.
Fairfield County Office, 831 College Avenue, Lancaster, OH	October 15.
Oklahoma City Hilton Northwest, 2945 Northwest Expressway, Oklahoma City, OK	October 15.
Red Lion North, 1415 NE Third Street, Bend, OR	October 18.
PA Game Commission Auditorium, 2001 Elmerton Avenue, Harrisburg, PA	October 17.

Location	Date
USDA Conference Room, 60 Quaker Lane, Warwick, RI	October 17.
Hampton Inn Harbison, 1–26 and Harbison Boulevard, Columbia, SC	October 17.
Crossroads Hotel and Convention Center, 100 4th Street SW, Huron, SD	October 17.
Milan Ag Museum Meeting Room, 3 Ledbetter Gate Road, Milan, TN	October 16.
Frank W. Mayborn Civic & Convention Center, 3303 North 3rd Street, Temple, TX	October 17.
Utah Department of Agriculture, 350 North Redwood Road, Salt Lake City, UT	October 15.
U.S. Forest Service, Northeastern Forest Experiment Station, 705 Spear Street, Burlington, VT	October 16.
Randolph Farm Pavilion, River Road, PO Box 9081, Virginia State University, Petersburg, VA	October 15.
Joint Center for Higher Education, 665 N. Riverpoint Boulevard, Spokane, WA	October 21.
Days Inn, 2000 Sutton Lane, Sutton, WV (Flatwoods Exit off I–79)	October 16.
USDA Conference Room, 6515 Watts Road, Room 209, Madison, WI	October 18.
Agricultural Learning Resource Center (Mills/Evansville Rooms), 2011 Fairgrounds Road, Casper, WY	October 18.

To obtain additional information about a specific forum, contact the following individual:

Location	Contact person	Phone	Address
Montgomery, AL	Ronnie D. Murphy	334–887–4535	USDA NRCS, 665 Opelika Road, P O Box 311, Auburn, AL 36830–0311.
	Robert Springer	334–279–3550	USDA FSA, Sterling Center, Suite 600, 4121 Carmichael Road, Montgomery, AL 36106.
Fairbanks, AK	Charles W. Bell	907–271–2424	USDA NRCS, 949 East 36th Avenue, Suite 400, Anchorage, AK 99508–4362.
	Karen O. Lee	907–745–7982	USDA FSA, 800 West Evergreen, Suite 216, Palmer, AK 99645–6389.
Mesa, AZ	Mike Somerville	602–280–8808	USDA NRCS, Suite 800, 3003 North Central Ave., Phoenix, AZ 85012–2945.
	Robert A. Picano	602–640–5200	USDA FSA, 77 East Thomas Rd., Suite 240, Phoenix, AZ 85012–3318.
Little Rock, AR	Thomas H. Wehri	501–324–5445	USDA NRCS, Federal Office Building, Rm. 5404, 700 West Capitol Ave., Little Rock, AR 72201–3228.
	Wayne Perryman	501–324–5220	USDA FSA, New Federal Bldg., Suite 5102, Little Rock, AK 72201–3225.
Sacramento, CA	Hershel R. Read	916–757–8215	USDA NRCS, 2121–C 2nd Street, Suite 102, Davis, CA 95616–5475.
	John G. Smythe	916–498–5311	USDA FSA, 1303 J Street, Suite 300, Sacramento, CA 95814–2916.
Longmont, CO	Duane L. Johnson	303–236–2886	USDA NRCS, 655 Parfet Street, Room E200C, Lakewood, CO 80215–5517.
	Robert L. Eisenach	303–236–2866	USDA FSA, 655 Parfet St., Suite E301, Lakewood, CO 80215.
Windsor, CT	Margo L. Wallace	203–487–4013	USDA NRCS, 16 Professional Park Road, Storrs, CT 06268–1299.
	Vincent Majchier	860–285–8483	USDA FSA, 88 Day Hill Road, Windsor, CT 06095–1778.
Dover, DE	Elesa K. Cottrell	302–678–4160	USDA NRCS, 1203 College Park Drive, Suite 101, Dover, DE 19904–8713.
	William D. Clifton	302–678–2547	USDA FSA, 1201 College Park Drive, Suite A, Dover, DE 19904–8713.
Gainesville, FL	T. Niles Glasgow	352–338–9500	USDA NRCS, 2614 NW 43rd Street, Gainesville, FL 32606–6611.
	Tim Manning	352–379–4500	USDA FSA, 4440 N.W. 25th Pl., Suite 1, Gainesville, FL 32606.
Moultrie, GA	Earl Cosby	706–546–2272	USDA NRCS, Federal Bldg. Box 13, 355 East Hancock Ave, Athens, GA 30601–2769.
	Grady Johnson	706–546–2266	USDA FSA, Federal Bldg., Room 102, 355 East Hancock Ave., Athens, GA 30601–2775.
Maite, GU	Joan Perry (Director)	9–011–671–472–7490	USDA NRCS, Suite 602 FHB Bldg., 400 Route 8, Maite, GU 96927.
	Jo-Anna Nakata	808–541–2644	USDA FSA.
Honolulu, HI	Kennneth M. Kaneshiro.	808–541–2601	USDA NRCS, 300 Ala Moana Blvd., Rm. 4316, P.O. Box 50004, Honolulu, HI 96850–0002.
	Jo-Anna Nakata	808–541–2644	USDA FSA, 300 Ala Moana Blvd., Rm. 5106, P.O. Box 50008, Honolulu, HI 96850.
Nampa, ID	Luana E. Kiger	208–334–1601	USDA NRCS, 3244 Elder Street, Rm. 124, Boise, ID 83705–4711.
	Richard R. Rush	208–378–5650	USDA FSA, 3220 Elder Street, Boise, ID 83705–4771.
Springfield, IL	Thomas W. Christensen.	217–398–5267	USDA NRCS, 1902 Fox Drive, Champaign, IL 61820–7335.
	Stephen Scates	217–492–4180	USDA FSA, P.O. Box 19273, Springfield, IL 62794–9723.
Indianapolis, IN	Robert L. Eddleman	317–290–3200	USDA NRCS, 6013 Lakeside Blvd., Indianapolis, IN 46278–2933.
	Robert Peacock	317–290–3030	USDA FSA, 5891 Lakeside Blvd., Indianapolis, IN 46278.
Des Moines, IA	Leroy Brown Jr	515–284–6655	USDA NRCS, 693 Federal Bldg., 210 Walnut Street, Des Moines, IA 50309.
	Tom Grau	515–254–1540	USDA FSA, 10500 Buena Vista Court, Des Moines, IA 50322.
Salina, KS	James Habiger	913–823–4565	USDA NRCS, 760 South Broadway, Salina, KS 67401.
	Adrian Polansky	913–539–3531	USDA FSA, 3600 Anderson Avenue, Manhatten, KS 66503–2511.
Lexington, KY	Billy W. Milliken	606–224–7350	USDA NRCS, 771 Corporate Drive, Suite 110, Lexington, KY 40503–5479.
	Hampton Henton	606–224–7601	USDA FSA, 771 Corporate Drive, Suite 100, Lexington, KY 40503–5478.

Location	Contact person	Phone	Address
Alexandria, LA	Donald W. Gohmert	318–473–7751	USDA NRCS, 3737 Government Street, Alexandria, LA 71302–3727.
	Willie Cooper	318–473–7721	USDA FSA, 3737 Government Street, Alexandria, LA 71302–3395.
Orono, ME	M. Darrel Dominick	207–866–7241	USDA NRCS, 5 Godfrey Drive, Orono, ME 04473.
	G. Arnold Roach	207–990–9140	USDA FSA, 444 Stillwater Avenue, P.O. Box 406, Bangor, ME 04402–0406.
Wye Mills, MD	Jeri Berc	410–757–0861	USDA NRCS, John Hanson Business Center, 339 Bush's Frontage Rd, Suite 301, Annapolis, MD 21401–5534.
	James Voss	410–381–4550	USDA FSA, 8335 E. Guilford Road, Suite E, Columbia, MD 21406.
Amherst, MA	Cecil Currin	413–253–4351	USDA NRCS, 451 West Street, Amherst, MA 01002–2995.
	Charles Costa	413–256–0232	USDA FSA, 445 West Street, Amherst, MA 01002–2957.
Lansing, MI	James R. Spacey	517–337–6701	USDA NRCS, Room 101, 1405 S. Harrison Road, East Lansing, MI 48823–5243.
	Chris White	517–337–6701	USDA FSA, 3001 Collidge Road, Suite 100, East Lansing, MI 48823–6321.
St. Cloud, MN	William Hunt	612–290–3675	USDA NRCS, 600 Farm Credit Services Bldg., 375 Jackson Street, St. Paul, MN 55101–1854.
	Wally Sparby	612–290–3675	USDA FSA, 400 Farm Credit Services Bldg., 375 Jackson Street, St. Paul, MN 55101–1854.
Jackson, MS	Homer L. Wilkes	601–965–5205	USDA NRCS, Suite 1321, Federal Bldg., 100 West Capitol Street, Jackson, MS 39629–1399.
	Norris Faust	601–965–4300	USDA FSA, 6310 I–55 North, Jackson, MS 39236–4995.
Columbia, MO	Roger Hansen	314–876–0901	USDA NRCS, Parkade Center Suite 250, 601 Business Loop 70W, Columbia, MO 65203–2546.
	Brad Epperson	573–876–0925	USDA FSA, 601 Business 70 W, Suite 225, Columbia, MO 65203.
Miles,City, MT Great Falls, MT.	Richard J. Gooby	406–587–6813	USDA NRCS, Federal Building, Rm. 443, 10 East Babcock St., Bozeman, MT 59715–4704.
	Bruce E. Nelson	406–587–6872	USDA FSA, 10 East Babcock St., Rm 557, Bozeman, MT 59715.
Grand Island, NE	Steven K. Chick	402–437–5302	USDA NRCS, Federal Bldg., Rm. 152, 100 Centennial Mall N., Lincoln, NE 68508–3866.
	Dan Steinkruger	402–437–5581	USDA FSA, 7131 A Street, Lincoln, NE 68510.
Reno, NV	William Goddard	702–784–5863	USDA NRCS, 301 Longley Lane, Building F, Suite 201, Reno, NV 89511.
	Wendell Newman	702–784–5411	USDA FSA, 1755 E. Plumb Lane, Suite 202, Reno, NV 89502.
Concord, NH	Dawn W. Genes	603–868–7581	USDA NRCS, Federal Building, Durham, NH 03824–1499.
	James McConaha	603–224–7941	USDA FSA, 22 Bridge St., 4th Floor, Concord, NH 03301–4987.
Mt. Holly, NJ	Wayne Maresch	908–246–1205	USDA NRCS, 1370 Hamilton Street, Somerset, NJ 08873–3157.
	Debra Borie-Holtz	609–298–3446	USDA FSA, 163 Route 130, Bordentown, NJ 08505.
Albuquerque, NM	Rosendo Trevino III	505–761–4400	USDA NRCS, 6200 Jefferson NE, Suite 305, Albuquerque, NM 27609–6293.
	Larry K. Burnett	505–761–4900	USDA FSA, 6200 Jefferson St., NE, Albuquerque, NM 27609–6296.
Raleigh, NC	Richard A. Gallo	919–873–2101	USDA NRCS, 4405 Bland Road, Suite 205, Raleigh, NC 27609.
	Sam Coley	919–790–2958	USDA FSA, 4407 Bland Road, Suite 175, Raleigh, NC 27609.
Dickinson, ND Jamestown, ND Minot, ND.	Scott Hoag	701–250–4421	USDA NRCS, Federal Building Room 278, 220E Rosser Avenue, P O Box 1458, Bismarck, ND 58502.
	Scott B. Stofferahn	701–239–5205	USDA FSA, 1025 28th St., SW, Fargo, ND 58103.
Syracuse, NY	Richard Swenson	315–477–6504	USDA NRCS, 441 South Salina Street, Suite 354, Syracuse, NY 13202–2450.
	Marc A. Smith	315–477–6303	USDA FSA, 441 South Salina Street, Suite 356, Syracuse, NY 13202.
Lancaster, OH	Daniel L. Conrad	614–469–6962	USDA NRCS, 200 North High Street, Room 522, Columbus, OH 43215.
	Steve Maurer	614–469–6735	USDA FSA, Rm 540 Federal Bldg., 299 North High St., Columbus, OH 43215.
Oklahoma City, OK	Ronnie C. Clark	405–742–1200	USDA NRCS, USDA Agriculture Bldg., Suite 203, Stillwater, OK 74074–2624.
	Terry L. Peach	405–742–1130	USDA FSA, 100 USDA, Suite 102, Stillwater, OK 74074–2653.
Bend, OR	Robert J. Graham	503–414–3201	USDA NRCS, 101 SW Main, Suite 1300, Portland, OR 97204–3221.
	Jack L. Sainsbury	503–692–6830	USDA FSA, 7620 SW Mohawk, Tulatin, OR 97062–8121.
Harrisburg, PA	Janet L. Oertly	717–782–2202	USDA NRCS, One Credit Union Place, Suite 340, Harrisburg, PA 17110–2993.
	William Baumgartner	717–782–4547	USDA FSA, One Credit Union Place, Suite 320, Harrisburg, PA 17110–2994.
Warwick, RI	Denis G. Nickel	401–828–1300	USDA NRCS, 60 Quaker Lane, Suite 46, Warwick, RI 02886–0111.
	Paul Brule	401–828–8232	USDA FSA, 60 Quaker Lane, Suite 40, Warwick, RI 02886–0111.
Columbia, SC	Mark W. Berkland	803–765–5681	USDA NRCS, 1835 Assembly Street, Strom Thurmond Federal Bldg., Columbia, SC 29201–2489.
	Laurie C. Lawson	803–806–3830	USDA FSA, 1927 Thurmod Mall, Suite 100, Columbia, SC 29201–2375.
Huron, SD	Dean F. Fisher	605–352–1200	USDA NRCS, Federal Building, 200 4th Street SW, Huron, SD 57350–2475.
	Michael W. O'Connor	605–352–1160	USDA FSA, 200 4th St., SW, Room 308, Huron, SD 57350–2478.
Milan, TN	Jerry S. Lee	615–736–5471	USDA NRCS, 675 US Courthouse, 801 Broadway, Nashville, TN 37203–3878.

Location	Contact person	Phone	Address
	Dave McDole	615–736–5555	USDA FSA, 579 Federal Bldg., 801 Broadway, Nashville, TN 37203.
Temple, TX	Harry W. Oneth	817–774–1231	USDA NRCS, WR Poage Federal, Bldg. 101 S. Main Street, Temple, TX 76501–7682.
	Harold Bob Bennett	409–260–9207	USDA FSA, P O Box 2900, College Station, TX 77841.
Salt Lake City, UT	Phillip J. Nelson	801–524–5050	USDA NRCS, Wallace F Bennett Federal Bldg., Rm. 4402, 125 S. State Street, Salt Lake City, UT 84138.
	James I. Humlicek	801–524–5013	USDA FSA, 125 S. State St., Room 4239, Salt Lake City, UT 84138–1189.
Burlington, VT	John C. Titchner	802–951–6796	USDA NRCS, 69 Union Street, Winooski, VT 05404–1999.
	James W. Monahan	802–658–2803	USDA FSA 346 Shelburne St., Executive Square Office Bldg., Burlington, VT 05401–4995.
Petersburg, VA	Margaret Doetzer	804–287–1691	USDA NRCS, Culpeper Bldg., Suite 209, 1606 Sanata Rosa Road, Richmond, VA 23229–5014.
	Donald Davis	804–287/1500	USDA FSA Culpeper Bldg., Suite 138, 1606 Santa Rosa Road, Richmond, VA23229.
Spokane, WA	Lynn A. Brown	509–353–2337	USDA FSA, West 316 Boone Avenue, Suite 450, Spokane, WA 99201–2348.
	Larry R. Albin	509–353–2307	USDA FSA, 316 West Boone Ave., Spokane, WA 99201–2350.
Sutton, WV	Roger L. Bensey Jr	304–291–4153	USDA NRCS, 75 High Street, Room 301, Morgantown, WV 26505.
	Billy Burke	304–291–4351	USDA FSA, 75 High St., P O Box 1049, Morgantown, WV 26507–1049.
Madison, WI	Patricia S. Leavenworth.	608–264–5577	USDA NRCS, 6515 Watts Road, Suite 200, Madison, WI 53719–2726.
	Doug Caruso	608–276–8732	USDA FSA, 6515 Watts Road, Suite 100, Madison, WI 53719–2726.
Casper, WY	Lincoln E. Burton	307–261–6453	USDA NRCS, Federal Office Bldg., 100 East ''B'' Street, Rm. 3124, Casper, WY 82601–1911.
	Carl E. Jensen	307–261–5231	USDA NRCS, 951 Werner Court, Suite 130, Casper, WY 82601–1307.

The United States Department of Agriculture (the Department), Natural Resources Conservation Service (NRCS) and Farm Service Agency (FSA) will conduct 54 public forums whereby interested individuals can provide comments and ideas on the proposed rules that have been published in the Federal Register to implement the conservation provisions of the Federal Agriculture Improvement and Reform Act of 1996 (the 1996 Act). These rules include: Highly Erodible Land/Wetland Conservation (Federal Register, August 27, 1996. (Volume 61, No. 167) Rules and Regulations, pp. 43943– 43946), Conservation Reserve Program (CRP)(Federal Register, September 23, 1996. (Volume 61, No. 185) Rules and Regulations, pp. 49697–49711), and Environmental Quality Incentives Program (EQIP).

The NRCS held nine public forums, located across the country, in July and August of 1994 to listen to the public's comments on changes that were needed in the 1995 Farm Bill and to better understand the needs of the public served by programs related to conservation of natural resources. The Department considered the comments and suggestions received in the 1994 forums when developing its recommendations for the 1995 Farm Bill. After lengthy debate within the Congress, the 1996 Farm Bill was passed by the Congress and was cited as the Federal Agriculture Improvement and Reform Act of 1996 (the 1996 Act). The President signed into law the 1996 Act on April 4, 1996.

Following the passage of the 1996 Act, the NRCS conducted public forums in these same nine locations to gather ideas on ways to implement the conservation provisions of the 1996 Act. Now that the program rules have been published in the Federal Register for public comment, the Department wants to support the public comment process by conducting additional listening forums.

Summary of the 1996 Act and the Rules which will be Discussed at the Public Forums

Conservation Reserve Program

The Conservation Reserve Program(CRP) encourages farmers to plant permanent areas of grass and trees on land that is subject to erosion, to improve soil, water and wildlife resources.

The 1996 Act:

- Allows up to 36.4 million acres to be enrolled at any one time. New enrollments can replace expired or terminated contracts.
- Allows owners or operators who entered into a contract before 1995 to terminate contracts on certain acres after giving written notice. Contracts must have been in effect for at least five years. Lands with high environmental values are not eligible for early release.

The CRP Proposed Rule

- Allows owners or operators who entered into a contract before January 1, 1995, to terminate their contract, if the contract had been in effect for at least five years. Under the statute, there is a 60-day waiting period before the application to terminate is effective. This termination will not relieve the participant of liability for a pre-existing contract violation.
- Limits the amount of acreage enrolled with an Erodibility Index of less than 8 to the following which may be eligible:
- Acreage devoted to special practices under the continuous sign-up.
- Acreage designated as cropped wetlands.
- Certain acreage enrolled in the Water Bank Program (WBP) during the last year of the WBP contract.
- Acreage located in a conservation priority area.
- Limits haying or grazing of acreage enrolled in the CRP to instances such as drought or similar emergencies.
- Outlines lands which are not eligible for early termination. These lands include: filter strips, grass waterways, riparian areas, field windbreaks, shelterbelts, shallow water areas for wildlife, bottom land timber, acreage with an erodibility index of more than 15, lands within an average distance of 100 feet of a permanent stream or other body of water, lands with useful life easements, and other

lands of high environmental value (including wetlands) as determined by the Secretary.

• Expands the list of acreage ineligible for early termination to also include: all wetlands, not just those enrolled under sign-up 8 and 9 criteria, land subject to frequent flooding, any wetland buffers required to protect the functions and values for wetland acreage, and Environmental Protection Agency (EPA)-designated wellhead protection areas.

• Modifies existing criteria to include cropped wetlands and certain acreage enrolled in the Water Bank Program (WBP).

• Proposes to base rental rates on the relative productivity of soils within each county, and the average of the past three years of local dryland cash rent or the cash rent equivalent.

• Encourages restoration of wetlands by offering up to 25 percent of the costs incurred. This is in addition to the 50-percent cost share provided to establish approved cover.

• Proposes to restrict the total area in a State that may be designated as a conservation priority area to no more than 10 percent of the cropland in the State.

• Allows producers who want to restore wetlands enrolled in the CRP to transfer acreage from the Conservation Reserve Program to the Wetlands Reserve Program, without penalty, if the acreage is found to be suitable.

Environmental Quality Incentives Program

The Environmental Quality Incentives Program (EQIP) is a new program which combines the functions of the Agricultural Conservation Program, Water Quality Incentives Program, Great Plans Conservation Program, and the Colorado River Basin Salinity Control Program.

EQIP is funded at $130 million in fiscal year 1996 and $200 million annually thereafter. Livestock-related conservation practices will receive 50 percent of program funding.

The 1996 Act

• Establishes conservation priority areas where significant water, soil, and related natural resource problems exist, in cooperation with state and federal agencies and State Technical Committees.

• Gives higher priority to areas where state or local governments offer financial or technical assistance, or where agricultural improvements will help meet water quality objectives.

• Establishes 5- to 10-year contracts to provide technical assistance and pay up to 75 percent of the costs of conservation practices such as manure management systems, pest management, and erosion control.

• Defines land eligible for EQIP contracts as agricultural land that poses a serious problem to soil, water, and/or related resources.

• Does not allow large livestock operations (to be defined through a public rule-making process) to be eligible for cost-share assistance for animal waste management facilities. However, they do remain eligible for technical assistance.

• Requires activities under the contract to be carried out according to a conservation plan.

• Limits total cost-share and incentive payments to any person to $10,000 annually, and to $50,000 for the life of the contract.

The Proposed EQIP Rule

• Sets forth that the purposes of the program will be achieved by farmers and ranchers who voluntarily develop conservation plans and enter into contracts with the Commodity Credit Corporation (CCC) to carry out the needed conservation practices and land-use adjustments within a specified time schedule.

• Allocates fifty percent of the EQIP funding available to practices relating to livestock production.

• Offers the program in priority areas throughout the Nation, using the services of the NRCS, county and state committees of the Farm Service Agency (FSA), and the Cooperative State Research, Education, and Extension Service (CSREES).

• Sets forth the requirements for participant eligibility and eligible land.

• Develops guidance for designation of priority areas.

• Outlines the process for selecting priority areas and conducting a needs assessment.

• Allows for program assistance to target other significant natural resource concerns outside of approved and funded priority areas.

• Allows for a continuous sign-up. CCC will rank and select the offers of producers during designated periods. To rank and select the highest priority applicants, NRCS on behalf of CCC, will evaluate using criteria that are based on national guidance and developed with the advice of a local work group to give a higher priority to projects that maximize environmental benefits per dollar expended.

• Outlines the producer's responsibilities in regards to a conservation plan and contract.

• Delegates the responsibility of determining what constitutes a large confined livestock operation to the State Technical Committee who will advise the State Conservationist. (CCC particularly solicits public comment on the definition of what constitutes a large confined livestock operation.)

• Describes eligible practices.

• Describes upcoming program outreach and educational efforts.

• Allows a producer to seek technical assistance from NRCS or other qualified sources which may include agricultural producers, certified crop advisors, agricultural cooperatives, and other technical consultants.

• Sets forth payment limitation criteria.

• Addresses the requirements for EQIP contracts.

• Addresses the participant's responsibility for conservation practice and operation maintenance.

• Addresses rates for cost-share and incentive payments.

• Addresses the procedures to be followed for contract violations and termination.

Highly Erodible Land (HEL) Conservation Compliance

The 1996 Act

• Directs USDA employees who are providing on-site technical assistance to work with landowners to correct an observed potential compliance problem. Landowners will have up to one year to take corrective action before a violation is reported.

• Encourages farmers to maintain records of residue measurement, including those provided by a third party. Where appropriate, NRCS will use these measurements when conducting annual status reviews to determine erosion levels.

• Authorizes county committees to provide relief in cases of undue economic hardship.

• Revises ''good faith'' to ensure penalties are commensurate with violations.

• Provides for expedited variances related to weather, pest, and disease problems and establishes a time period to render a decision on whether to grant those variances.

• Requires a measurement of soil erosion on a highly erodible field prior to the implementation of a conservation system, based on estimated average annual soil erosion rates.

• Provides for a revision or modification of a conservation plan by a person if the same level of treatment is maintained.

• Requires that highly erodible land exiting the Conservation Reserve

Program not be held to a higher conservation compliance standard than similar cropland in the same area.

The Interim Rule

- Lists factors that NRCS will consider when a landowner requests a variance related to weather, pest, or disease problems.
- Specifies that when fields are combined, the part of the new field that was previously a highly erodible field shall continue to be subject to the highly erodible land requirements.
- Clarifies that the adequacy of a conservation system will be evaluated according to whether it conforms to the NRCS field office technical guide in use at the time that the plan or system is developed or revised.
- Outlines procedures to be used to evaluate the adequacy of conservation systems for achieving substantial reduction in soil erosion on land with and without cropping history.
- Sets forth that conservation field trials included in a person's conservation plan must have prior approval by NRCS and must be documented in the person's conservation plan specifying the limited time period during which the field trial is in effect.
- Outlines the factors to be considered by the FSA State Committee in determining whether to grant a person's request for relief based on undue economic hardship in implementing a conservation system.

Wetland Conservation (Swampbuster)

The 1996 Act

- Expands areas where mitigation can be used. This allows individuals to work with producers, conservation districts or other relevant entities to select the best area for mitigating wetlands.
- Provides more options for mitigation, including restoration, enhancement, or creation, as long as wetland functions and values are maintained.
- Encourages effective and timely use of ''minimal effect'' determinations. This change allows the NRCS, working with State Technical Committees, to identify practices that have a minimal effect on the environment and put them on a ''fast track.''
- Stipulates that wetland conversion activities, authorized by a permit issued under Section 404 of the Clean Water Act, which make agriculture production possible, will be accepted for farm bill purposes if they were adequately mitigated.
- Revises the concept of ''abandonment'' to ensure that as long as land is used for agriculture, a certified prior converted cropland designation remains in effect. When done under an approved plan, landowners with farmed wetlands (FW) and farmed wetland pasture (FWP) may allow an area to revert to wetland status, and convert it back to an FW or FWP for agricultural purposes without violating the Swampbuster provision.
- Provides that a certified wetland delineation will remain in effect until the person requests a new determination and certification.
- Ensures producers the right to request and appeal a certified wetland determination.
- Allows the Farm Service Agency (FSA) to waive a person's ineligibility for benefits if FSA believes the person acted in good faith and without intent to violate the wetland provisions.
- Provides the Secretary with authority to identify for individual producers which programs are affected by Swampbuster violations and how much the penalty is.
- Establishes a pilot program for wetland mitigation banking in order to allow USDA to assess how well mitigation banking works for agriculture.
- Expands the definition of agricultural land contained in the interagency wetlands memorandum of agreement to include not only cropland and pasture land, but also tree farms, rangeland, native pasture land, and other land used for livestock production.
- Repeals the requirements for consultation with the Fish and Wildlife Service (FWS).
- Provides that benefits of affiliates of a business enterprise who violate highly erodible land or wetland conservation provisions will be reduced in proportion to the interest held by the affiliate in the business enterprise.

The Interim Rule

- States more precisely the variety of wetland types found in the agricultural landscape.
- Describes how wetland types relate to particular exemptions from ineligibility.
- Provides that when a person requests relief on the basis of action that was conducted in good faith, USDA may consider whether the person has a record of violating the wetland provisions of these regulations or other Federal, State, or local wetland provisions.
- Adds that NRCS may accept the assistance of other Federal agencies to carry out the wetland responsibilities. For example, specific portions of the rule state that NRCS will consult with FWS at the State level to develop a process for implementation of the wetland conservation provisions.
- Describes the procedure for certification of wetland determinations and specifies that certified wetland determinations will meet current Federal mapping conventions.
- Amends to provide that the determination of prevalence of hydrophytic vegetation will be made in accordance with the current Federal wetland delineation methodology in use at the time of the determination. This change assures that the NRCS, FWS, Environmental Protection Agency and Army Corps of Engineers will utilize consistent and up-to-date technical standards and criteria.
- Creates a new exemption for land that was certified as having been converted prior to December 23, 1985 (prior converted croplands), but had returned to wetland characteristics after that date. This exemption provides that if certain requirements are met, a prior converted cropland will not be considered abandoned for purposes of implementation of these provisions.
- Allows areas that NRCS determined to be manipulated but were not completely converted prior to December 23, 1985 (farmed wetlands and farmed wetland pastures), and which may revert to wetland status through a voluntary restoration, enhancement or creation action, will not be considered abandoned for purposes of implementing these regulations.
- Provides that a person who received an individual permit under section 404 of the Clean Water Act after December 23, 1985, and met certain sequencing requirements, is exempt from the ineligibility provisions of these regulations. However, this rule, provides that a person whose conversion activity is encompassed by a nationwide or regional general permit issued pursuant to section 404 of the Clean Water Act may not be exempt under these regulations. USDA will evaluate whether any mitigation was required, and whether the wetland functions and values lost by the conversion activity were adequately replaced before USDA decides whether the conversion activity is exempt from ineligibility under these regulations.
- Provides that a person may remain eligible if the wetland functions and values are adequately mitigated in accordance with several requirements, including that the person implement a mitigation plan approved by NRCS.
- Sets forth that NRCS may accept the assistance of the memorandum of

agreement agencies in implementing these regulations.

Paul W. Johnson,

Chief, Natural Resources Conservation Service.

Grant Buntrock,

Administrator, Farm Service Agency.

[FR Doc. 96–25749 Filed 10–4–96; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

7 CFR Chapter VI

Farm Service Agency

7 CFR Chapter VII

AGENCY: Natural Resources Conservation Service and Farm Service Agency, USDA.

ACTION: Announcement of forums, on interim rules.

SUMMARY: The United States Department of Agriculture's, Natural Resources Conservation Service (NRCS) and Farm Service Agency (FSA) announced elsewhere in today's Federal Register forums on the implementation of the conservation provisions of the Federal Agriculture Improvement and Reform Act of 1996 (the 1996 Act), which includes: Highly Erodible Land Compliance, Wetlands Conservation, Conservation Reserve Program (CRP), and the Environmental Quality Incentives Program (EQIP).

FOR FURTHER INFORMATION CONTACT:

Lloyd Wright, USDA/NRCS, Phone: 202–720–1845
Cheryl Zavodny, USDA/FSA, Phone: 202–720–7333.

SUPPLEMENTARY INFORMATION: The United States Department of Agriculture (the Department), Natural Resources Conservation Service (NRCS) and Farm Service Agency (FSA) will conduct 54 public forums where interested individuals can provide comments and ideas on the implementation of the conservation provisions of the Federal Agriculture Improvement and Reform Act of 1996 (the 1996 Act), which includes: Highly Erodible Land/Wetland Conservation (Federal Register, August 27, 1996. (Volume 61, No. 167) Rules and Regulations, pp. 43943–43946), Conservation Reserve Program (CRP)(Federal Register, September 23, 1996. (Volume 61, No. 185) Rules and Regulations, pp. 49697–49711), and Environmental Quality Incentives Program (EQIP).

The public is invited to attend the meetings to provide brief oral comments. All are encouraged to provide detailed written comments concerning the implementation of the 1996 Act which are due on or before October 22, 1996. Those who wish to speak at a meeting may make arrangements in advance by calling the state contact listed for the meeting. In addition, individuals wishing to provide oral presentations may sign-up at the forum, as time permits.

For information on the dates and locations of these forums, please consult the announcement of forums on proposed rules, located elsewhere in today's Federal Register.

Paul W. Johnson,

Chief, Natural Resources Conservation Service.

Grant Buntrock,

Administrator, Farm Service Agency.

[FR Doc. 96–25809 Filed 10–4–96; 8:45 am]

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federal register

Monday
October 7, 1996

Part IX

The President

Proclamation 6926—National Breast Cancer Awareness Month, 1996

Proclamation 6927—National Domestic Violence Awareness Month, 1996

Federal Register
Vol. 61, No. 195
Monday, October 7, 1996

Presidential Documents

Title 3—

The President

Proclamation 6926 of October 3, 1996

National Breast Cancer Awareness Month, 1996

By the President of the United States of America

A Proclamation

Each year we set aside the month of October as a time to assess the toll that breast cancer takes on our society and the progress we have made in our battle to overcome it. For those of us who have lost loved ones to this disease—mothers, wives, daughters, sisters, and friends—the battle holds special urgency.

Breast cancer remains the second leading cause of all deaths among women ages 40 to 55. In 1996, a woman will die from breast cancer every 12 minutes, and 184,300 women in the United States will be diagnosed with the disease. Every one of these diagnoses changes not only that woman's life, but the lives of all who love and care for her.

We have embarked on an all-out assault to combat this threat. The Federal Government has nearly doubled funding for breast cancer research, detection, and treatment since 1993, from $271 million to $476 million in the Department of Health and Human Services alone. And in response to requests from 2.6 million of our Nation's citizens, we launched the National Action Plan on Breast Cancer, an innovative public-private partnership to develop a national strategy for prevention, education and care.

We can be proud of the progress we are making in the fight against breast cancer. During the most recent 5-year period for which data are available (1989-1993), age-adjusted mortality rates for white women fell almost 6 percent. Although mortality rates among African American women are still increasing, the rate of increase has slowed to 1 percent, compared to 16 percent during the 1980's.

One of our most successful weapons in the fight against breast cancer is early detection. The new Mammography Quality Standards Act now ensures that every woman who obtains a mammogram to detect breast cancer in its earliest, curable, stages can be certain that facilities meet the highest quality standards for equipment and personnel. We are implementing the National Breast and Cervical Cancer Early Detection Program to make free or low-cost mammography available to medically under-served women. The First Lady launched an education campaign to inform and encourage older women to use Medicare's mammography screening benefit. And to improve early detection, we are transferring imaging technologies from the space, defense, and intelligence communities.

I urge women throughout our nation to have appropriate mammograms, to perform routine self-examination, and to take advantage of the latest in preventive medical care. Armed with this commonsense approach and the promising advances in research and treatment, we can look forward with confidence to the day when breast cancer is finally eradicated.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim October 1996 as National Breast Cancer Awareness Month. I call upon government officials, businesses, communities, volunteers, educators, and all the people of the United States to celebrate the successes we have had in advancing our knowledge of

breast cancer, and to reaffirm our commitment to continue to work together to fight this disease.

IN WITNESS WHEREOF, I have hereunto set my hand this third day of October, in the year of our Lord nineteen hundred and ninety-six, and of the Independence of the United States of America the two hundred and twenty-first.

William J. Clinton

[FR Doc. 96–25897
Filed 10–4–96; 11:28 am]
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Presidential Documents

Proclamation 6927 of October 3, 1996

National Domestic Violence Awareness Month, 1996

By the President of the United States of America

A Proclamation

Domestic violence threatens the very core of what we hold dear. Millions of women and children throughout our nation are plagued by the terror of family violence each year, and approximately 20 percent of all hospital emergency room visits by women result from such violence. Family violence is a crime that transcends race, religion, ethnicity, and economic stature, and one of its greatest tragedies is its effect on our young people: as many as 3 million children witness violence in their homes each year.

We must never give up in our efforts to transform despair into hope for the women and families across this country who suffer violence at home. We must encourage all Americans to increase public awareness and understanding of domestic abuse as well as the needs of its victims. My Administration is fully engaged in this struggle, coordinating our efforts through the Violence Against Women Office at the Department of Justice and through the Department of Health and Human Services.

Legislation enacted during the past several years is also helping to overcome the scourge of domestic violence. The Violence Against Women Act that I signed into law has given law enforcement critical new tools with which to prosecute and punish criminals who intentionally prey upon women and children. The Interstate Stalking Punishment and Prevention Act of 1996, enacted just last month, makes it a Federal crime for any stalker to cross State lines to pursue a victim, whether or not there is a protection order in effect, whether or not an actual act of violence has been committed, and whether or not the stalker is the victim's spouse. And I am pleased that the Congress has just taken action to keep guns out of the hands of people with a history of domestic violence.

My Administration has also worked to increase the support available for battered women and other victims of domestic violence, including the elderly. In February, I announced the creation of a 24-hour, toll-free National Domestic Violence Hotline, 1-800-799-SAFE. The response to this service has been overwhelming, and the hotline has already received over 50,000 calls—the majority from women and men who have never before reached out for assistance. This year, we will also provide increased and unprecedented resources for battered women's shelters, domestic violence prevention efforts, and children's counseling services.

There is still much more to do, however. The welfare reform legislation that I recently signed recognizes the special needs of domestic violence victims, and I urge all States to accept the option of implementing the new law's Family Violence provisions. I have also directed the Department of Health and Human Services and the Department of Justice to develop guidance for States and assist them in implementing the provisions. As we help families move from welfare to work, we must ensure that they remain safe from violence in their homes and are given the support they need to achieve independence.

As a result of these and other efforts at the national, State, and local levels, we are one step closer to eliminating domestic violence and building in its place a brighter, more secure future for our families and loved ones.

I salute all those whose efforts are helping us in this endeavor and pay special tribute to the survivors of domestic violence whose courage is an inspiration to us all. I urge all Americans to join me in working toward the day when no person raises a hand in violence against a family member.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim October 1996 as National Domestic Violence Awareness Month. I call upon all Americans to observe this month by demonstrating their respect and gratitude for all those individuals who unselfishly share their experiences, skills, and talents with those affected by domestic violence.

IN WITNESS WHEREOF, I have hereunto set my hand this third day of October, in the year of our Lord nineteen hundred and ninety-six, and of the Independence of the United States of America the two hundred and twenty-first.

William J. Clinton

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The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

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- Massachusetts; published 8-8-96

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LIST OF PUBLIC LAWS

This is a list of public bills from the 104th Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–523–6641. The text of laws is not published in the **Federal Register** but may be ordered in individual pamphlet form (referred to as ''slip laws'') from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–2470).

H.R. 3074/P.L. 104–234

To amend the United States-Israel Free Trade Area Implementation Act of 1985 to provide the President with additional proclamation authority with respect toarticles of the West Bank or Gaza Strip or a qualifying industrial zone. (Oct. 2, 1996; 110 Stat. 3058)

S. 919/P.L. 104–235

Child Abuse Prevention and Treatment Act Amendments of 1996 (Oct. 3, 1996; 110 Stat. 3063)

S. 1675/P.L. 104–236

Pam Lychner Sexual Offender Tracking and Identification Act of 1996 (Oct. 3, 1996; 110 Stat. 3093)

S. 1965/P.L. 104–237

Comprehensive Methamphetamine Control Act of 1996 (Oct. 3, 1996; 110 Stat. 3099)

S. 2101/P.L. 104–238

Federal Law Enforcement Dependents Assistance Act of 1996 (Oct. 3, 1996; 110 Stat. 3114)

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CFR CHECKLIST

This checklist, prepared by the Office of the Federal Register, is published weekly. It is arranged in the order of CFR titles, stock numbers, prices, and revision dates.

An asterisk (*) precedes each entry that has been issued since last week and which is now available for sale at the Government Printing Office.

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Title	Stock Number	Price	Revision Date
1, 2 (2 Reserved)	(869–028–00001–1)	$4.25	Feb. 1, 1996
3 (1995 Compilation and Parts 100 and 101)	(869–028–00002–9)	22.00	[1] Jan. 1, 1996
4	(869–028–00003–7)	5.50	Jan. 1, 1996
5 Parts:			
1–699	(869–028–00004–5)	26.00	Jan. 1, 1996
700–1199	(869–028–00005–3)	20.00	Jan. 1, 1996
1200–End, 6 (6 Reserved)	(869–028–00006–1)	25.00	Jan. 1, 1996
7 Parts:			
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27–45	(869–028–00008–8)	11.00	Jan. 1, 1996
46–51	(869–028–00009–6)	13.00	Jan. 1, 1996
52	(869–028–00010–0)	5.00	Jan. 1, 1996
53–209	(869–028–00011–8)	17.00	Jan. 1, 1996
210–299	(869–028–00012–6)	35.00	Jan. 1, 1996
300–399	(869–028–00013–4)	17.00	Jan. 1, 1996
400–699	(869–028–00014–2)	22.00	Jan. 1, 1996
700–899	(869–028–00015–1)	25.00	Jan. 1, 1996
900–999	(869–028–00016–9)	30.00	Jan. 1, 1996
1000–1199	(869–028–00017–7)	35.00	Jan. 1, 1996
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10 Parts:			
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280–399	(869–028–00057–6)	13.00	Apr. 1, 1996
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220–499	(869–028–00079–7)	13.00	May 1, 1996
500–699	(869–028–00080–1)	14.00	May 1, 1996
700–899	(869–028–00081–9)	13.00	May 1, 1996
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§§ 1.401–1.440	(869–028–00089–4)	31.00	Apr. 1, 1996
§§ 1.441-1.500	(869-028-00090-8)	22.00	Apr. 1, 1996
§§ 1.501–1.640	(869–028–00091–6)	21.00	Apr. 1, 1996
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§§ 1.851–1.907	(869–028–00093–2)	26.00	Apr. 1, 1996
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*900–1899	(869–028–00111–4)	20.00	July 1, 1996
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1910 (§§ 1910.1000 to end)	(869–026–00115–4)	22.00	July 1, 1995
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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 Apr. 1, 1990 to Mar. 31, 1996. The CFR volume issued April 1, 1990, should be retained.

[5] No amendments to this volume were promulgated during the period July 1, 1991 to June 30, 1996. The CFR volume issued July 1, 1991, should be retained.