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# federal register

Tuesday
October 28, 1997

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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.

## OFFICE OF PERSONNEL MANAGEMENT

### 5 CFR Part 213

**RIN 3206–AH91**

### Fellowship and Similar Appointments in the Excepted Service

**AGENCY:** Office of Personnel Management.

**ACTION:** Final rule.

**SUMMARY:** The Office of Personnel Management (OPM) is consolidating single-agency excepted service authorities for filling positions associated with fellowships, residencies, industry-exchange, student-stipend, and similar programs by establishing two Governmentwide authorities in their place. One authority covers fellowship-type programs, while the other applies to student employees who are paid stipends under special statutory provisions.

**EFFECTIVE DATE:** November 28, 1997.

**FOR FURTHER INFORMATION CONTACT:** Sylvia Cole on (202) 606–0830, TDD (202) 606–0023, or FAX (202) 606–2329.

**SUPPLEMENTARY INFORMATION:** In OPM's continuing efforts to simplify the Federal appointment system, we are reducing the overall number of excepted service authorities. As part of this initiative we are reviewing all appointing authorities that were established to meet specific agency needs, to determine if exception is still appropriate. Where it is, we are identifying the situations where individual agency authorities share enough of a common basis that they can be consolidated into a single Governmentwide appointing authority that would apply to all agencies.

On August 11, 1997 (62 FR 42943), OPM published proposed regulations to establish a new Schedule A authority 213.3102(r) that would consolidate single-agency authorities covering a variety of fellowship, internship, residency, industry-exchange and similar programs. We proposed to establish a separate Schedule A authority 213.3102(s) for positions filled by student-employees assigned to Government hospitals, clinics or medical or dental laboratories to whom agencies pay stipends authorized under 5 U.S.C. 5351–5356. These positions are placed in Schedule A because it is impracticable to examine for them.

Our proposal also included a conforming amendment to the service limits on temporary appointments in 5 CFR 213.104, to include the two new appointing authorities in the list of exceptions cited in 5 CFR 213.104(b)(3)(ii).

We received one comment from an agency in support of the proposed regulations and are adopting them as final regulations with no change.

### Documentation on SF–50, Notification of Personnel Action

For appointments made under Schedule A, section 213.3102(r), fellowship and similar programs, agencies should cite Legal Authority Code W9S on the SF 50, Notification of Personnel Action. For appointments made under Schedule A, section 213.3102(s), student-employees paid stipends, agencies should use Legal Authority Code W9T.

### Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities (including small businesses, small organizational units, and small governmental jurisdictions) because the regulations apply only to appointment procedures used to appoint certain employees in Federal agencies.

### List of Subjects in 5 CFR Part 213

Government employees, Reporting and recordkeeping requirements.

U.S. Office of Personnel Management.

**Janice R. Lachance,**

*Acting Director.*

Accordingly, OPM is amending 5 CFR part 213 as follows:

## PART 213—EXCEPTED SERVICE

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

**Authority:** 5 U.S.C. 3301 and 3302, E.O. 10577, 3 CFR 1954–1958 Comp., p. 218; § 213.101 also issued under 5 U.S.C. 2103; § 213.3102 also issued under 5 U.S.C. 3301, 3302, 3307, 8337(h) and 8456; E.O. 12364, 47 FR 22931, 3 CFR 1982 Comp., p. 185; and 38 U.S.C. 4301 *et seq.*

2. In § 213.104 paragraph (b)(3)(ii) is revised to read as follows:

**§ 213.104 Special provisions for temporary, intermittent, or seasonal appointments in Schedule A, B, or C.**

* * * * *

(b) * * *

(3) * * *

(ii) Positions are filled under an authority established for the purpose of enabling the appointees to continue or enhance their education, or to meet academic or professional qualification requirements. These include the authorities set out in paragraphs (r) and (s) of § 213.3102 and paragraph (c) of § 213.3202, and authorities granted to individual agencies for use in connection with internship, fellowship, residency, or student programs.

* * * * *

3. In § 213.3102, paragraphs (r) and (s) are added to read as follows:

**§ 213.3102 Entire executive civil service.**

* * * * *

(r) Positions established in support of fellowship and similar programs that are filled from limited applicant pools and operate under specific criteria developed by the employing agency and/or a non-Federal organization. These programs may include: internship or fellowship programs that provide developmental or professional experiences to individuals who have completed their formal education; training and associateship programs designed to increase the pool of qualified candidates in a particular occupational specialty; professional/industry exchange programs that provide for a cross-fertilization between the agency and the private sector to foster mutual understanding, an exchange of ideas, or to bring experienced practitioners to the agency; residency programs through which participants gain experience in a Federal clinical environment; and programs that require a period of Government service in exchange for educational, financial or other assistance. Appointments under this authority may not exceed 4 years.

(s) Positions with compensation fixed under 5 U.S.C. 5351–5356 when filled by student-employees assigned or attached to Government hospitals, clinics or medical or dental laboratories. Employment under this authority may not exceed 4 years.

* * * * *

[FR Doc. 97–28437 Filed 10–27–97; 8:45 am]

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## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. 96–NM–155–AD; Amendment 39–10177; AD 97–22–06]**

**RIN 2120–AA64**

## Airworthiness Directives; Airbus Model A300, A310, and A300–600 Series Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD), applicable to all Airbus Model A300, A310, and A300–600 series airplanes, that requires performing a ram air turbine (RAT) extension test; removing and disassembling the RAT uplock mechanism; performing an inspection to detect corrosion of the RAT uplock mechanism, and replacement with a new assembly, if necessary; and cleaning all the parts of the RAT control shaft and its bearing component parts. This amendment is prompted by reports indicating that the RAT did not extend during ground testing, due to corrosion in the uplock pin/shaft and the needle bearing of the RAT. The actions specified by this AD are intended to detect and correct such corrosion of the RAT, which could result in failure of the RAT to deploy and subsequent loss of emergency hydraulic power to the flight controls in the event that power is lost in both engines.

**DATES:** Effective December 2, 1997.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 2, 1997.

**ADDRESSES:** The service information referenced in this AD may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Manager, International Office, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

**SUPPLEMENTARY INFORMATION:** A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to all Airbus Model A300, A310, and A300–600 series airplanes was published in the **Federal Register** on February 19, 1997 (62 FR 7380). That action proposed to require a RAT extension test during ground testing; removal and disassembly of the RAT uplock mechanism; a visual inspection to detect corrosion of the RAT uplock mechanism, and replacement of the assembly with new parts, if necessary; and cleaning of the lever assembly and its associated parts.

### Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

### Revision of Descriptive Language

One commenter points out that throughout the proposed AD it references ram air turbine (RAT) uplock assembly and lever assembly as if these assemblies are the same unit. However, Airbus Service Bulletin A310–29–2076, dated April 1, 1996 (which is referenced in the proposal as an appropriate source of service information) refers to these assemblies as separate units. The FAA finds that clarification of this point is necessary.

The FAA finds that ''RAT uplock assembly'' does not appear in the proposed AD, but ''RAT lever assembly'' does. The FAA has determined that the phrase ''RAT uplock mechanism,'' which includes both the lever assembly and uplock unit, provides a more complete description, than the phrase, ''RAT lever assembly.'' The FAA has revised the final rule to include reference to ''RAT uplock mechanism'' and added a new NOTE 2 to provide a definition of that phrase.

### Clarification of Requirements

One commenter points out that paragraph (a) of the proposed AD references accomplishment of paragraph (a)(1), (a)(2), (a)(3), and (a)(4) of the AD; however, paragraph (a)(3) and (a)(4) of the proposed AD are missing. The FAA acknowledges that it inadvertently included a reference to paragraphs (a)(3) and (a)(4) in paragraph (a) of the proposed AD. The FAA has revised paragraph (a) of the final rule to delete these references.

### Request To Defer Replacement of Corroded Parts

One commenter requests that paragraph (a)(2)(ii) be revised to allow reinstallation of the corroded part and require its replacement within 30 days. The commenter points out that operators would have to stock every part of the subject assembly at the inspection stations (which is not very practical), or its airplanes would have unnecessary time out-of-service while waiting for parts. The FAA has reconsidered replacing corroded parts prior to further flight. The FAA finds that the cleaning and lubrication procedures of the RAT uplock mechanism can be accomplished on a temporary basis, in lieu of replacement of corroded parts. However, unlike the 12-month compliance time recommended in the Airbus service bulletins specified as the appropriate service information for this AD, the FAA has determined that the corroded parts must be replaced within 30 days following accomplishment of the cleaning and lubrication. The FAA finds that this compliance time represents the maximum interval of time allowable wherein the subject replacement could reasonably be accomplished, uncorroded parts could be obtained, and an acceptable level of safety could be maintained. Therefore, the FAA has revised paragraph (a)(2)(ii) of the final rule accordingly.

### Revision of Compliance Time in Paragraph (a) of this AD

In addition, the compliance time specified in paragraph (a) of this AD has been revised to state, ''30 months since date of manufacture,'' rather than ''30 months total time-in-service,'' as stated in the proposed rule. This change clarifies that the compliance is to be determined based on calendar time, without regard to the amount of time for which the airplane is operated.

### Conclusion

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes previously described. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

## Cost Impact

The FAA estimates that 80 Airbus Model A300, A310, and A300–600 series airplanes of U.S. registry will be affected by this AD, that it will take approximately 10 work hours per airplane to accomplish the required actions, and that the average labor rate is $60 per work hour. Required parts would be provided by the manufacturer at no cost to the operator. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $48,000, or $600 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the 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 adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

## List of Subjects in 14 CFR Part 39

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

## Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

### § 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

**97–22–06 Airbus Industrie:** Amendment 39–10177. Docket 96-NM–155-AD.

*Applicability:* All Model Airbus Model A300, A310, and A300–600 series airplanes, certificated in any category.

**Note 1:** This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (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 detect and correct corrosion of the ram air turbine (RAT) uplock pin/shaft and needle that could result in failure of the RAT to deploy and subsequent loss of emergency hydraulic power to the flight controls in the event that power is lost in both engines, accomplish the following:

(a) Prior to the accumulation of 30 months since the date of manufacture, or within 3 months after the effective date of this AD, whichever occurs later: Accomplish the requirements of paragraphs (a)(1) and (a)(2) of this AD in accordance with Airbus Service Bulletin A300–29–0108, dated April 1, 1996 (for Model A300 series airplanes); A310–29–2076, dated April 1, 1996 (for Model A310 series airplanes); or A300–29–6037, dated April 1, 1996 (for Model A300–600 series airplanes); as applicable. Thereafter, repeat these actions at intervals not to exceed 30 months.

(1) Perform a RAT extension test on the ground, in accordance with the procedures specified in the Maintenance Manual.

(2) Disassemble and remove the uplock mechanism of the RAT and perform a visual inspection of the uplock mechanism to detect corrosion, in accordance with the applicable service bulletin.

**Note 2:** For the purposes of this AD, the RAT uplock mechanism includes both the lever assembly and uplock unit.

(i) If no corrosion is detected: Prior to further flight, clean and lubricate the uplock mechanism and its associated parts, reinstall the assembly, and perform a retraction/extension/retraction of the RAT, in accordance with the applicable service bulletin.

(ii) If any corrosion is detected in any part of the uplock mechanism, prior to further flight, accomplish either paragraph (a)(2)(ii)(A) or (a)(2)(ii)(B) of this AD in accordance with the applicable service bulletin.

(A) Replace the uplock mechanism with a new part and perform a retraction/extension/retraction of the RAT, in accordance with the applicable service bulletin. Or

(B) Clean and lubricate the uplock mechanism and its associated parts. Within 30 days following accomplishment of this cleaning and lubrication, replace the uplock mechanism with a new part and perform a retraction/extension/retraction of the RAT.

(b) Initial accomplishment of the actions required by paragraph (a) of this AD that have been performed in accordance with Airbus All Operator Telex (AOT) 29–16, Revision 01, dated January 10, 1996, is considered acceptable for compliance with the initial RAT extension test and an initial visual inspection as required by paragraph (a) of this AD. However, the first repetitive inspection, as required by paragraph (a) of this AD, must be performed within 30 months after that RAT extension test and visual inspection were conducted, and repeated thereafter at intervals not to exceed 30 months.

(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, Standardization Branch, ANM–113, 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, Standardization Branch, ANM–113.

**Note 3:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(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.

(e) The actions shall be done in accordance with Airbus Service Bulletin A300–29–0108, dated April 1, 1996; Airbus Service Bulletin A310–29–2076, dated April 1, 1996; or Airbus Service Bulletin A300–29–6037, dated April 1, 1996; as applicable. This 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. Copies may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**Note 4:** The subject of this AD is addressed in French airworthiness directive 95–163–182 (B) R2, dated June 5, 1996.

(f) This amendment becomes effective on December 2, 1997.

Issued in Renton, Washington, on October 20, 1997.

**Darrell M. Pederson,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 97–28320 Filed 10–27–97; 8:45 am]

BILLING CODE 4910–13–P

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## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. 97–NM–243–AD; Amendment 39–10175; AD 97–22–04]**

**RIN 2120–AA64**

## Airworthiness Directives; Boeing Model 747 and 767 Series Airplanes Equipped With General Electric (GE) CF6–80C2 Engines

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule; request for comments.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD) that is applicable to certain Boeing Model 747 and 767 series airplanes. This action requires revising the FAA-approved Airplane Flight Manual (AFM) to prohibit the use of certain fuels, and either replacing the existing placard on the door of the fueling control panel with a new placard; or replacing all dribble flow fuel nozzles (DFFN) with standard fuel nozzles, which terminates the requirements for a placard and AFM revision. This amendment is prompted by a report of an engine flameout during certification testing due to the use of JP–4 or Jet B fuel. The actions specified in this AD are intended to prevent such engine flameouts and consequent engine shutdown.

**DATES:** Effective November 12, 1997.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 12, 1997.

Comments for inclusion in the rules docket must be received on or before December 29, 1997.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97–NM–243–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Edward Hormel, Aerospace Engineer, Propulsion Branch, ANM–140S, Seattle Aircraft Certification Office, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2681; fax (425) 227–1181.

**SUPPLEMENTARY INFORMATION:** The FAA has received a report indicating that, during certification testing of a General Electric (GE) CF6–80C2 engine on which dribble flow fuel nozzles (DFFN) were installed, an engine flameout occurred on a McDonnell Douglas Model MD–11 series airplane operating with JP–4 fuel. The engine flameout occurred at 33,000 feet following a throttle movement from ''cruise thrust'' to ''idle.'' The report indicated that the engine restarted successfully.

Additionally, results of a GE transient engine model revealed that the subject engines, on which a low emissions combustor and DFFN's have been installed, have zero transient margin for flameout when operating with JP–4 fuel.

Boeing Model 747 and 767 series airplanes equipped with GE Model CF6–80C2 engines on which DFFN's have been installed, in combination with the use of wide cut fuels (i.e., JP–4 or Jet B fuel) may result in a single- or multi-engine flameout and consequent engine shutdown.

### Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Alert Service Bulletins 747–11A2052 (for Model 747 series airplanes) and 767–11A0031 (for Model 767 series airplanes), both dated September 11, 1997, which describe procedures for removing the existing placard on the door of the fueling control panel and replacing it with a new placard that prohibits the use of JP–4 and Jet B fuels (wide cut fuels).

Additionally, these alert service bulletins describe procedures for removing the DFFN's and replacing them with standard fuel nozzles. Accomplishment of this replacement on the operator's entire fleet eliminates the need for a placard that prohibits the use of wide cut fuels.

### Explanation of the Requirements of the Rule

Since an unsafe condition has been identified that is likely to exist or develop on Boeing Model 747 and 767 series airplanes equipped with GE CF6–80C2 engines that incorporate certain DFFN's, this AD is being issued to prevent engine flameout and consequent shutdown of the engine due to the use of JP–4 or Jet B fuel. This AD requires either replacement of the existing placard on the door of the fueling control panel with a new placard that prohibits the use of JP–4 and Jet B fuels, or the removal and replacement of the DFFN's with standard fuel nozzles. Replacement of all DFFN's with standard fuel nozzles on the operator's entire fleet terminates the requirements for a placard that prohibits the use of wide cut fuels and the AFM revision. These actions are required to be accomplished in accordance with the alert service bulletins described previously.

This AD also requires a revision to the Limitations Section of the FAA-approved Airplane Flight Manual (AFM) to prohibit the use of JP–4 and Jet B fuels.

### Interim Action

This is considered interim action until final action is identified, at which time the FAA may consider further rulemaking.

### Determination of Rule's Effective Date

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

### Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this 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 under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the 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 that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the rules docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 97–NM–243–AD.'' The postcard will be date stamped and returned to the commenter.

## Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the rules docket. A copy of it, if filed, may be obtained from the rules docket at the location provided under the caption **ADDRESSES**.

## List of Subjects in 14 CFR Part 39

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

## Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

### § 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

**97–22–04 Boeing:** Amendment 39–10175. Docket 97–NM–243–AD.

*Applicability:* Model 747 series airplanes having line positions 679 through 1117 inclusive, and Model 767 series airplanes having line positions 158 through 661 inclusive; equipped with General Electric (GE) CF6–80C2 engines, on which dribble flow fuel nozzles (DFFN's) having General Electric part number 9331M72P33, 9331M72P34, or 9331M72P41, have been installed; certificated in any category.

**Note 1:** This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) 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 engine flameout and consequent shutdown due to the use of JP–4 or Jet B fuel, accomplish the following:

(a) Within 14 days after the effective date of this AD, revise Section 1 of the Limitations Section of the FAA-approved Airplane Flight Manual (AFM) to include the following procedures. This may be accomplished by inserting a copy of this AD in the AFM.

(1) Revise paragraph 1 of the Engine Fuel System section to read as follows: ''The fuel designation is General Electric (GE) Specification D50TF2, as revised. Fuel conforming to commercial jet fuel specification ASTM–D–1655, Jet A, and Jet A–1 are authorized for unlimited use in this engine. Fuels conforming to MIL–T–5624 grade JP–5 and MIL–T–83113 grade JP–8 are acceptable alternatives. The engine will operate satisfactorily with any of the foregoing fuels or any mixture thereof.'' And,

(2) Add the following sentence to paragraph 2 of the Engine Fuel System section: ''The use of Jet B and JP–4 fuel is prohibited.''

(b) Within 30 days after the effective date of this AD, accomplish the requirements of paragraph (b)(1) or (b)(2) of this AD, in accordance with either Boeing Alert Service Bulletin 747–11A2052 (for Model 747 series airplanes) or 767–11A0031, (for Model 767 series airplanes), both dated September 11, 1997; as applicable.

(1) Remove the existing placard on the door of the fueling control panel and replace it with a new placard that restricts the use of JP–4 and Jet B fuels (wide cut fuels), in accordance with the applicable alert service bulletin. Or

(2) Remove the DFFN's, and replace them with standard fuel nozzles, in accordance with the applicable alert service bulletin. When an operator's entire fleet has had all DFFN's replaced with standard fuel nozzles, the AFM revision required by paragraph (a) of this AD may be removed from the AFM and the placard required by paragraph (b)(1) of this AD may be removed from each airplane.

(c) As of the effective date of this AD, no person shall install any DFFN's having General Electric part number 9331M72P33, 9331M72P34, or 9331M72P41, on any airplane, unless the requirements of paragraph (b)(1) of this AD have been accomplished.

(d) 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, Seattle 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, Seattle ACO.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(e) 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.

(f) Except as provided by paragraph (a) of this AD, the actions shall be done in accordance with Boeing Alert Service Bulletin 747–11A2052, dated September 11, 1997, or Boeing Alert Service Bulletin 767–11A0031, dated September 11, 1997, as applicable. This 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. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment becomes effective on November 12, 1997.

Issued in Renton, Washington, on October 17, 1997.

**Darrell M. Pederson,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 97–28317 Filed 10–27–97; 8:45 am]

BILLING CODE 4910–13–U

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 39**

**[Docket No. 96–NM–95–AD; Amendment 39–10176; AD 97–22–05]**

**RIN 2120–AA64**

## Airworthiness Directives; McDonnell Douglas Model DC–9 Series Airplanes and C–9 (Military) Series Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment adopts a new airworthiness directive applicable to certain McDonnell Douglas Model DC–9 series airplanes and C–9 (military) series airplanes, that requires modification of the emergency internal release system of the tailcone and the accessory compartment. This amendment is prompted by a report that, due to failure of the tailcone release system, the tailcone did not deploy on an airplane during an emergency evacuation. The actions specified by this AD are intended to ensure that the emergency internal release system of the tailcone performs its intended function in the event of an emergency evacuation. The actions also are intended to prevent people on board the airplane from striking their heads on exposed metal frames in the tailcone area, which could cause injury and delay or impede their evacuation during an emergency.

**DATES:** Effective December 2, 1997.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 2, 1997.

**ADDRESSES:** The service information referenced in this AD may be obtained from The Boeing Company, Douglas Products Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Dept. C1–L51 (2–60). This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Albert H. Lam, Aerospace Engineer, Systems and Equipment Branch, ANM–130L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712; telephone (562) 627–5346; fax (562) 627–5210.

**SUPPLEMENTARY INFORMATION:** A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain McDonnell Douglas Model DC–9 series airplanes and C–9 (military) series airplanes was published in the **Federal Register** on September 13, 1996 (61 FR 48433). That action proposed to require modification of the emergency internal release system of the tailcone and the accessory compartment.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Two commenters support the proposed rule.

### Requests To Revise the Compliance Times of the Proposed Modifications

One commenter requests that the compliance time for accomplishing the proposed modifications be extended from the proposed 36 months to 4 years. The commenter states that such an extension will allow the modifications to be accomplished during a regularly scheduled heavy maintenance check and will allow time for procurement of additional modification kits. The commenter also states that such an extension will allow time for revising the affected manual; training of inspection and maintenance personnel; drafting, checking, and approving engineering documents; and testing and debugging the proposed modifications.

Another commenter requests that the compliance times be shortened to 12 months. This commenter suggests that the proposed compliance times may be too long to fly with the potential of failure of the emergency internal release system of the tailcone.

The FAA does not concur with either of these commenters' request. In developing an appropriate compliance time for these modifications, the FAA considered not only the degree of urgency associated with addressing the unsafe condition, but the availability of required parts and the practical aspect of installing the required modifications within an interval of time that parallels normal scheduled maintenance for the majority of affected operators. The manufacturer has advised that an ample number of required parts will be available for modification of the U.S. fleet within the proposed compliance period. Further, the FAA estimates that the affected airplanes will undergo two heavy maintenance checks during the proposed compliance time. In addition, the FAA finds that the 36-month compliance time is sufficient for operators to train their personnel and to incorporate the modifications into various documents. However, under the provisions of paragraph (c) of the final rule, the FAA may approve requests for adjustments to the compliance time if data are presented to justify such an adjustment.

### Request To Remove Modification Requirement

Two commenters state that the modification specified in McDonnell Douglas DC–9 Service Bulletin 53–257, Revision 1, dated February 9, 1996 [which is referenced in paragraph (a) of the proposal as the appropriate source of service information] is difficult to accomplish and only adds more problems to the existing tailcone release system. One of these commenters contends that the tailcone release system described in the referenced service bulletin is unacceptable for an emergency exit system. This commenter also contends that the subject modification cannot be accomplished on airplanes equipped with aft ventral airstairs.

From these comments, the FAA infers that the commenters are requesting that the proposed modification in paragraph (a) of the AD be removed from the final rule. The FAA does not concur. The FAA acknowledges that there were some problems associated with accomplishing the modification in accordance with the original issue of McDonnell Douglas DC–9 Service Bulletin 53–257, dated May 18, 1994. However, the FAA finds that these problems were addressed and corrected in Revision 1 of this service bulletin. The FAA recognizes that Revision 1 of the service bulletin does not address airplanes on which the aft ventral airstair handle has not been deactivated. However, based on a survey conducted by McDonnell Douglas, the FAA finds that affected operators are willing to deactivate the aft ventral airstair handle to accommodate the modification required by this AD. In addition, paragraph (c) of the AD contains a provision for requesting approval of an alternative method of compliance to address these types of unique circumstances.

### Request To Add a New Requirement

One commenter requests that paragraph (b) of the proposed AD be revised to include procedures for adding

protective padding between the added ceiling panel and beams, and on all other beams in the path of exiting passengers. The commenter contends that installation of ceiling panels [as required by paragraph (b) of the AD] provides a false sense of security and guidance to the flight attendants and evacuees. The commenter states that the ceiling panels could be damaged easily by tall and/or unruly passengers during emergency egress, which could expose the beams and supporting structure. Thus other passengers could strike their heads against the overhead beams. The commenter also states that the ceiling panels could detach from its support structure during an actual emergency, and consequently, also allow exposure of the beams and supporting structure. Further, the commenter states that the ceiling panels could fall in the path of the passengers that are exiting from the airplane. The FAA does not concur. The FAA has determined that installation of ceiling panels on the lower side of three frames and installation of a protective pad on the last frame in the aft accessory compartment provides an acceptable level of safety. In addition, the FAA finds that such an installation is comparable to other panel installations throughout the airplane. However, under provisions of paragraph (c) of the final rule, operators may apply for approval of an alternative methods of compliance if sufficient justification is presented to the FAA.

**Request To Address Deficiencies With Existing Tailcone Release System**

One commenter states that the existing tailcone release system contains many design and reliability deficiencies. The commenter points out that the proposed AD does not specify any requirements to replace or repair the existing tailcone release system. The commenter also contends that, due to such deficiencies, the new interior release handle [installed in accordance with the requirements of paragraph (b) of the proposed AD] will fail to perform its intended function. From this comment, the FAA infers that the commenter is requesting that the FAA address the problems associated with the existing tailcone release system in the proposed AD. The FAA does not concur. The FAA has previously issued several other AD's that concern the tailcone deployment system on Model DC–9 series airplanes, which was discussed previously in the Other Relevant Rulemaking Section in the preamble to the NPRM. Therefore, the FAA finds no change to the final rule is necessary.

**Request To Revise the Proposed Modification of the Emergency Internal Release System**

One commenter requests that the existing tailcone release system be replaced with an electro-mechanical system, which can be actuated from inside the airplane. The commenter states that it is more cost effective to install a modern and efficient system (i.e., electro-mechanical system), rather than a system with design technology standards that are 25 to 30 years old. The commenter also states that the existing system does not meet industry expectations. The FAA does not concur. The modification required by paragraph (b) of this AD was developed with operator, manufacturer, and FAA concurrence based on cost and technical feasibility. However, under the provisions of paragraph (c) of this AD, operators may apply for the approval of an alternative method of compliance, if sufficient justification is presented to the FAA.

**Request To Revise Various Manufacturer Manuals**

One commenter requests that the FAA require the manufacturer, rather than the affected operator(s), to update the affected Illustrated Parts Catalog, Airplane Maintenance Manual, Structural Repair Manual, and Wiring Diagram Manual to ensure continued airworthiness of the tailcone release system. The commenter states that an operator, who does not have ''experience'' with the modification required by the proposed AD, could enter erroneous information into these manuals. The FAA does not concur. The FAA finds that the subject service documents are not necessary to accomplish the modifications required by this AD. The FAA has been informed that the manufacturer is in the process of revising the DC–9 Airplane Maintenance Manual (AMM) to comply with the continued airworthiness requirements and will make the AMM available to operators.

**FAA's Conclusion**

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

**Cost Impact**

There are approximately 878 McDonnell Douglas Model DC–9 series airplanes and C–9 (military) series airplanes of the affected design in the worldwide fleet. The FAA estimates that 590 airplanes of U.S. registry will be affected by this AD.

The modification of the emergency internal release system will take approximately 7 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts will cost approximately $6,660 per airplane. Based on these figures, the cost impact of this modification required by this AD on U.S. operators is estimated to be $4,177,200, or $7,080 per airplane.

The modification of the accessory compartment will take approximately 10 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. For the 395 airplanes identified as ''Group I'' in the referenced service bulletin, required parts will cost approximately $1,777 per airplane. For the 195 airplanes identified as ''Group 2'' in the referenced service bulletin, required parts will cost $5,369 per airplane. Based on these figures, the cost impact of this modification required by this AD on U.S. operators of Group 1 airplanes is estimated to be $938,915, or $2,377 per airplane; and on U.S. operators of Group 2 airplanes is estimated to be $1,163,955, or $5,969 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the 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 adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

## List of Subjects in 14 CFR Part 39

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

## Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

### §39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

**97–22–05—McDonnell Douglas:** Amendment 39–10176. Docket 96–NM–95–AD.

*Applicability:* Model DC–9–10, –20, –30, –40, and –50 series airplanes and C–9 (military) series airplanes; as listed in McDonnell Douglas DC–9 Service Bulletin 53–257, Revision 1, dated February 9, 1996, and McDonnell Douglas DC–9 Service Bulletin 25–331, dated December 10, 1993; operating in a passenger or passenger/cargo configuration; certificated in any category.

**Note 1:** The requirements of this AD become applicable at the time an airplane operating in an all-cargo configuration is converted to a passenger or passenger/cargo configuration.

**Note 2:** This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise 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 ensure that the emergency internal release system of the tailcone performs its intended function in the event of an emergency evacuation, accomplish the following:

(a) For airplanes listed in McDonnell Douglas DC–9 Service Bulletin 53–257, Revision 1, dated February 9, 1996: Within 36 months after the effective date of this AD, modify the emergency internal release system of the tailcone in accordance with the service bulletin.

(b) For airplanes listed in McDonnell Douglas DC–9 Service Bulletin 25–331, dated December 10, 1993: Within 36 months after the effective date of this AD, modify the accessory compartment in accordance with the service bulletin.

(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.

(e) The actions shall be done in accordance with McDonnell Douglas DC–9 Service Bulletin 53–257, Revision 1, dated February 9, 1996, and McDonnell Douglas DC–9 Service Bulletin 25–331, dated December 10, 1993. This 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. Copies may be obtained from McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Department C1–L51 (2–60). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on December 2, 1997.

Issued in Renton, Washington, on October 17, 1997.

**Darrell M. Pederson,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 97–28319 Filed 10–27–97; 8:45 am]

BILLING CODE 4910–13–U

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## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. 97–NM–229–AD; Amendment 39–10179; AD 97–22–07]**

**RIN 2120–AA64**

## Airworthiness Directives; Boeing Model 737 Series Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule; request for comments.

**SUMMARY:** This amendment supersedes an existing airworthiness directive (AD), applicable to certain Boeing Model 737 series airplanes, that currently requires repetitive inspections to detect cracking of the lower skin at the lower row of fasteners in the lap joints of the fuselage, and repair of any cracking detected. This amendment requires that the inspections be accomplished at more frequent intervals. This amendment also adds a requirement for modification of the fuselage lap joints at certain locations, which constitutes terminating action for repetitive inspections of modified areas. This amendment is prompted by reports of numerous fatigue cracks in the lower skin of the fuselage lap joints at the lower row of fasteners. The actions specified in this AD are intended to prevent such fatigue cracking, which could result in sudden decompression of the airplane.

**DATES:** Effective November 12, 1997.

The incorporation by reference of certain publications, as listed in the regulations, is approved by the Director of the Federal Register as of November 12, 1997.

The incorporation by reference of Boeing Alert Service Bulletin 737–53A1177, dated November 8, 1994, as listed in the regulations, was approved previously by the Director of the Federal Register as of December 27, 1994 (59 FR 63716, December 9, 1994).

Comments for inclusion in the Rules Docket must be received on or before December 29, 1997.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97–NM–229–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Gregory L. Schneider or Nenita K. Odesa, Aerospace Engineers, Airframe Branch, ANM–120S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue, SW., Renton, Washington; telephone (425) 227–2028 or (425) 227–2557; fax (425) 227–1181.

**SUPPLEMENTARY INFORMATION:** On April 28, 1988, a Boeing Model 737 series airplane was involved in an accident in which a 15-foot long section of fuselage structure peeled open during flight. In light of this, the FAA initiated an Aging Fleet Program. The objective of that program is to identify and implement procedures to ensure the continuing structural airworthiness of aging transport category airplanes.

As part of the Aging Fleet Program, the airplane manufacturer conducted cyclic pressure (fatigue) tests to evaluate the performance of the various fuselage skin panel lap joint configurations. The fuselage skin panel joint consists of two adjacent panels that overlap each other longitudinally and are joined together by three rows of fasteners at the overlap (hence, lap joint). Cracks in the upper skin of the lap joint led to the structural failure that occurred in the 1988 accident discussed previously. These ''first generation'' lap joints, installed on early Model 737 series airplanes having line numbers 1–291, were modified by replacing the countersunk fasteners in the upper fastener row of the lap joint with protruding head fasteners to correct and prevent cracking in the upper skin of the lap joint. No cracking has been detected to date in the lower fastener row of these (modified)''first generation'' lap joints.

In 1994, tests were conducted on ''second generation'' lap joints; test results revealed cracks in the lower skin of this lap joint. The airplane manufacturer determined that these cracks were caused by increased stresses in this area due to the increased bending stresses associated with the installation of a doubler on the upper skin. This doubler was installed on ''second generation'' lap joints as an improvement to the lap joint to prevent cracks in the upper skin. This lap joint configuration, which incorporates the additional doubler, was installed on Model 737 series airplanes having line numbers 292 through 2565.

In light of results of these tests, the manufacturer inspected the lap joints of five aging airplanes and detected a total of 273 fatigue cracks. The use of eddy current inspection techniques were required as the cracks in the lower skin are not detectable visually due to the positioning of the lower skin between the upper skin and the circumferential tear strap. Many of these cracks were found to have occurred simultaneously at adjacent fastener hole locations in the lower skin of the fuselage lap joint.

This type of cracking of the lap joint is known as multiple site damage (MSD). MSD is characterized by the simultaneous presence of fatigue cracks in the same structural element (such as the lower skin panel of the lap joint). Coalescence of cracks at adjacent fastener holes in the lower skin can lead to sudden fracture and failure of the lap joint, which could result in rapid decompression of the airplane. Due to the reduction in the residual strength of a lap joint in the presence of MSD. This reduction of the structural integrity of the fuselage may occur at loads significantly below those that would be expected for structure having a single large crack. The accident discussed previously has demonstrated dramatically that small cracks acting together can have a significant effect on the residual strength of the aircraft structure.

**Issuance of Previous Rule**

On December 2, 1994, the FAA issued AD 94–25–05, amendment 39–9089 (59 FR 63716, December 9, 1994), applicable to certain Boeing Model 737 series airplanes, to require repetitive eddy current inspections to detect cracking of the lower skin at the lower row of fasteners in the lap joints of the fuselage between body stations 259.50 and 1016, and repair of any cracking detected. That AD was prompted by reports of fatigue cracking occurring simultaneously at adjacent fastener hole locations in the lower skin of the fuselage lap joint. The actions required by AD 94–25–05 are intended to prevent sudden decompression of the airplane due to undetected cracking of the fuselage skin.

**Actions Since Issuance of Previous Rule**

Since the issuance of AD 94–25–05, the FAA has received additional reports of fatigue cracking in the lower skin of the lap joints of the fuselage on airplanes previously inspected in accordance with that AD. The FAA received reports of numerous cracks on a number of airplanes that had accumulated between 52,000 and 78,000 total flight cycles and that had been inspected using low frequency eddy current (LFEC) inspection techniques. The majority of these cracks occurred at left and right stringers 4, 10, and 14.

The FAA also received recent reports indicating that extensive cracking was found on three airplanes on which high frequency eddy current (HFEC) inspections and modification of the lap joints had been accomplished in accordance with Revision 1 of Boeing Alert Service Bulletin 737–53A1177. Approximately eight months had elapsed since the initial LFEC inspections required by AD 94–25–05 had been accomplished. These airplanes had accumulated between 76,000 and 84,400 total flight cycles. The total number of cracks reported was between 246 and 360 on these three airplanes, and the majority of these cracks occurred at left and right stringers 4, 10, and 14. On one of these airplanes, cracking was found along a 111-inch section of stringer 4L at every fastener hole in the lower row of fasteners in the lower skin that had not been repaired during the previous LFEC inspection (82% of the total fastener holes).

In the preamble to AD 94–25–05, the FAA specified that the actions required by that AD were considered ''interim action'' and that the manufacturer was developing a modification to positively address the unsafe condition. The FAA indicated that it may consider further rulemaking action once the modification was developed, approved, and available. The manufacturer now has developed such a modification, and the FAA has determined that further rulemaking action is indeed necessary; this AD follows from that determination.

**Explanation of Relevant Service Information**

Since the issuance of AD 94–25–05, the FAA has reviewed and approved Boeing Alert Service Bulletin 737–53A1177, Revision 1, dated September 19, 1996; Revision 2, dated July 24, 1997; and Revision 3, dated September 18, 1997; which describe procedures for inspections similar to those specified in the original issue of the alert service bulletin. (The original issue of the alert service bulletin was cited in AD 94–25–05 as the appropriate source of service information).

Revision 1 of the alert service bulletin describes procedures for modification of the lap joints at the lower row of fasteners in the lower skin of the fuselage [reference Part III (''Preventive Change'') of the Accomplishment Instructions of the alert service bulletin].

The relevant changes in Revision 2 of the alert service bulletin include procedures for more frequent repetitive inspections of the lower skin at the lower row of fasteners in the lap joints of the fuselage.

For certain lap joint locations on Model 737–200 series airplanes only, Revision 2 of the alert service bulletin also describes procedures for an option to the modification (''Preventive Change'') described in Revision 1 of the alert service bulletin. This option [reference Part IV (''Lap Joint Repair'') of the Accomplishment Instructions of the alert service bulletin] involves installing a lap joint repair on the entire length of the skin panel at certain lap joint locations.

Revision 3 of the alert service bulletin is essentially the same as Revision 2; however, Revision 3 corrects a particular fastener size specified in Part IV of the Accomplishment Instructions of the alert service bulletin.

Accomplishment of the modification eliminates the need for the repetitive inspections only of those areas that have been modified. Accomplishment of the actions specified in the alert service bulletin is intended to adequately address the identified unsafe condition.

**FAA's Determinations**

Based on reports of numerous cracks detected on airplanes inspected previously, the FAA finds that, for certain airplanes, the repetitive LFEC inspections required currently by AD 94–25–05 must be accomplished at more frequent intervals to detect cracks that, in the presence of MSD, could propagate to the point of structural failure of the lap joints and result in rapid decompression of the airplane.

Based upon reports of extensive MSD found in the lower skin of the lap joints located at stringers 4, 10, and 14, there may be a significant reduction in the residual strength of these lap joints. Because of this reduction in strength, in combination with the possibility that cracks may go undetected due to human factors, the FAA finds that the reduced inspection interval provided by this AD may not be adequate to detect cracks which could propagate to the point of structural failure. As a result, for airplanes that have accumulated 70,000 or more total flight cycles, the FAA has concluded that modifications of the lap joints at stringers 4, 10, and 14 (as required by this AD) on which the most severe cracking has been detected, must be required on an emergency basis.

**Explanation of Requirements of Rule**

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of this same type design, this AD supersedes AD 94–25–05 to continue to require repetitive inspections to detect cracking of the lower skin at the lower row of fasteners in the lap joints of the fuselage, and repair of any cracking detected. This AD requires that the inspections be accomplished at more frequent intervals.

This AD also requires modification of the fuselage lap joints at certain locations. Accomplishment of the modification constitutes terminating action for the repetitive inspections only of those areas that have been modified in accordance with this AD.

The inspections and modification are required to be accomplished in accordance with the alert service bulletin described previously.

**Explanation of Compliance Time for Initial Inspection**

Operators should note that, for certain airplanes, the compliance time for accomplishment of the initial inspection required by this AD is approximately 120 days. That number of days is usually sufficient to allow for prior notice to the public and a brief comment period before adoption of a final rule. In this AD, however, that compliance time was selected because of:

- The large number of aircraft affected by the AD;
- The large number of work hours required to accomplish the inspection; and
- The availability of an adequate number of maintenance facilities able to accommodate scheduling the fleet for inspection.

A shorter compliance time might have resulted in the unnecessary removal of airplanes from service pending scheduling. Nevertheless, the FAA has determined that immediate adoption is necessary in this case because of the importance of initiating the required inspections and modification as soon as possible.

**Differences Between the AD and the Relevant Service Bulletins**

Operators should note that, for airplanes that have accumulated between 60,000 and 65,000 total flight cycles, the alert service bulletin specifies a repetitive inspection of 3,500 flight cycles until the airplane has accumulated 65,000 total flight cycles. However, for that group of airplanes, this AD requires that repetitive inspections be accomplished at intervals not to exceed 1,200 flight cycles. The FAA has determined that, because of the safety implications and consequences of multiple site damage associated with fatigue cracking of the fuselage skin, it is necessary to require earlier repetitive inspections to ensure the continued operational safety of the fleet.

For Boeing Model 737–200 series airplanes only, Part IV of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1177, Revision 3, dated September 18, 1997, recommends installation of a support cradle at station 540. However, this installation is not intended to support the weight of the airplane. Therefore, this AD does not require installation of this support cradle. In addition, to clarify the reference in the alert service bulletin for supporting the airplane in the jig position, paragraph (g)(2) of this AD explicitly requires that, prior to conducting the repair of the lap joint, the airplane be supported in the jig position, including support (removal) of the engine weight. This action is required to be accomplished in accordance with Boeing Document D6–15565, ''737 Structural Repair Manual (SRM),'' Chapter 51, Subject 51–50–1, Revision 70, dated July 5, 1997.

**Subsequent Rulemaking**

The FAA may consider separate rulemaking action for airplanes that have accumulated more than 70,000 total flight cycles to require modification of the lap joints at the remaining locations specified in Part III (''Preventive Change'') of the Accomplishment Instructions of the alert service bulletin.

In addition, for airplanes that have accumulated less than 70,000 total flight cycles, the FAA may consider requiring accomplishment of this modification at all locations specified in the alert service bulletin.

**Determination of Rule's Effective Date**

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

**Comments Invited**

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this 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 under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the 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 that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the rules docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 97–NM–229–AD.'' The postcard will be date stamped and returned to the commenter.

## Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the rules docket. A copy of it, if filed, may be obtained from the rules docket at the location provided under the caption **ADDRESSES.**

## List of Subjects in 14 CFR Part 39

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

## Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

**§ 39.13 [Amended]**

2. Section 39.13 is amended by removing amendment 39–9089 (59 FR 63716, December 9, 1994), and by adding a new airworthiness directive (AD), amendment 39–10179, to read as follows:

**97–22–07 Boeing:** Amendment 39–10179. Docket 97–NM–229–AD. Supersedes AD 94–25–05, Amendment 39–9089.

*Applicability:* Model Boeing 737 series airplanes having line numbers 292 through 2565 inclusive, certificated in any category.

**Note 1:** This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise 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 (i) 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 sudden decompression of the airplane, accomplish the following:

(a) Perform a low frequency eddy current inspection to detect cracking of the lower skin at the lower row of fasteners in the lap joints of the fuselage at the time specified in paragraph (b) or (c) of this AD, as applicable, in accordance with Part I (''Inspection'') of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1177, dated November 8, 1994; Revision 1, dated September 19, 1996; Revision 2, dated July 24, 1997; or Revision 3, dated September 18, 1997.

(b) For airplanes that have accumulated 70,000 total flight cycles or more as of the effective date of this AD: Perform the inspection required by paragraph (a) of this AD at the later of the times specified in paragraphs (b)(1) and (b)(2) of this AD.

(1) Within 100 flight cycles after the effective date of this AD.

(2) Within 300 flight cycles after the last inspection accomplished in accordance with AD 94–25–05, amendment 39–9089.

(c) For airplanes that have accumulated less than 70,000 total flight cycles as of the effective date of this AD: Perform the inspection required by paragraph (a) of this AD at the later of the times specified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Prior to the accumulation of 60,000 total flight cycles.

(2) At the earliest of the times specified in paragraph (c)(2)(i), (c)(2)(ii), and (c)(2)(iii) of this AD.

(i) Within 3,500 flight cycles after the last inspection accomplished in accordance with AD 94–25–05, amendment 39–9089.

(ii) Within 1,200 flight cycles after the effective date of this AD.

(iii) Prior to the accumulation of 70,300 total flight cycles.

(d) If any cracking is detected during the inspection required by paragraph (a) of this AD, prior to further flight, repair it in accordance with Part II (''Crack Repair'') of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1177, dated November 8, 1994; Revision 1, dated September 19, 1996; Revision 2, dated July 24, 1997; or Revision 3, dated September 18, 1997.

(e) Repeat the inspection required by paragraph (a) of this AD at the time specified in paragraph (e)(1) or (e)(2) of this AD, as applicable, until the modification required by paragraph (f) or (g) of this AD, as applicable, is accomplished.

(1) If the airplane had accumulated less than 70,000 total flight cycles at the time of the immediately preceding inspection, perform the next inspection within 1,200 flight cycles or prior to the accumulation of 70,300 total flight cycles, whichever occurs first.

(2) If the airplane had accumulated 70,000 or more total flight cycles at the time of the immediately preceding inspection, perform the next inspection within 300 flight cycles.

(f) Except as provided by paragraph (g) of this AD, modify the fuselage lap joints at the lower row of fasteners at stringer locations right/left stringer 4 between body station (BS) 360 and BS 1016; and right/left stringers 10 and 14 between BS 360 and BS 540, and between BS 727 and BS 1016; in accordance with Part III (''Preventive Change'') of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1177, Revision 1, dated September 19, 1996; Revision 2, dated July 24, 1997; or Revision 3, dated September 18, 1997; at the time specified in paragraph (h) of this AD. Accomplishment of this modification constitutes terminating action for the repetitive inspections only for the areas that have been modified in accordance with this AD.

(g) For Boeing Model 737–200 series airplanes only:

(1) Except as provided in paragraphs (g)(2) and (g)(3) of this AD, in lieu of accomplishing the modification (''Preventive Change'') specified in paragraph (f) of this AD, installation of the lap joint repair in accordance with Part IV (''Lap Joint Repair'') of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1177, Revision 3, dated September 18, 1997, at the locations specified in Part IV of the alert service bulletin, may be accomplished. Accomplishment of the repair constitutes terminating action for the repetitive inspections only for the areas that have been modified in accordance with this AD.

(2) Prior to conducting the repair, support the airplane in the jig position, including support (removal) of the engine weight, in accordance with Boeing Document D6–15565, ''737 Structural Repair Manual (SRM),'' Chapter 51, Subject 51–50–1, Revision 70, dated July 5, 1997.

**Note 2:** Chapter 51, Subject 51–50–1 of the referenced SRM references Subjects 51–50–2, 51–50–3, and 51–60 of the referenced SRM as additional sources of service information.

(3) Notwithstanding the Accomplishment Instructions of Boeing Alert Service Bulletin

737–53A1177, Revision 3, dated September 18, 1997, the repair described in paragraph (g)(1) of this AD may be accomplished without installing a support cradle at station 540.

(h) Accomplish the modification required by paragraph (f) or (g) of this AD, as applicable, at the latest of the times specified in paragraphs (h)(1), (h)(2), and (h)(3) of this AD.

(1) Prior to the accumulation of 70,000 total flight cycles.

(2) Within 600 flight cycles after the effective date of this AD.

(3) Within 80 days after the effective date of this AD.

(i) 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, Seattle ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

**Note 3:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(j) 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.

(k) The actions shall be done in accordance with Boeing Alert Service Bulletin 737–53A1177, dated November 8, 1994; Boeing Alert Service Bulletin 737–53A1177, Revision 1, dated September 19, 1996; Boeing Alert Service Bulletin 737–53A1177, Revision 2, dated July 24, 1997; Boeing Alert Service Bulletin 737–53A1177, Revision 3, dated September 18, 1997; and Boeing Document D6–15565, ''737 Structural Repair Manual (SRM),'' Chapter 51, Subject 51–50–1, Revision 70, dated July 5, 1997, which contains the following list of effective pages (NOTE: The issue date and revision level of the SRM are indicated only on the Title Page; no other page of the document contains this information.):

| Page No. | Revision level shown on page | Date shown on page |
|---|---|---|
| Title page | 70 | July 5, 1997. |
| 1 | Not shown | Feb. 5, 1989. |
| 2, 3, 11, 12 | Not shown | Aug. 5, 1988. |
| 4 | Not shown | Feb. 1, 1978. |
| 5, 6, 8–10 | Not shown | Aug. 1, 1968. |
| 7 | Not shown | Feb. 1, 1975. |

(1) The incorporation by reference of Boeing Alert Service Bulletin 737–53A1177, Revision 1, dated September 19, 1996; Boeing Alert Service Bulletin 737–53A1177, Revision 2, dated July 24, 1997; Boeing Alert Service Bulletin 737–53A1177, Revision 3, dated September 18, 1997; and Boeing Document D6–15565, ''737 Structural Repair Manual (SRM),'' Chapter 51, Subject 51–50–1, Revision 70, dated July 5, 1997; is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of Boeing Alert Service Bulletin 737–53A1177, dated November 8, 1994, was approved previously by the Director of the Federal Register as of December 27, 1994 (59 FR 63716, December 9, 1994).

(3) Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(l) This amendment becomes effective on November 12, 1997.

Issued in Renton, Washington, on October 21, 1997.

**Darrell M. Pederson,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 97–28347 Filed 10–27–97; 8:45 am]

BILLING CODE 4910–13–U

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## LIBRARY OF CONGRESS

## Copyright Office

## 37 CFR Part 201

**[Docket No. 97–5A]**

## Copyright Restoration of Works in Accordance With the Uruguay Round Agreements Act; NIE Corrections Procedure

**AGENCY:** Copyright Office, Library of Congress.

**ACTION:** Interim regulations with request for comments.

**SUMMARY:** The Copyright Office is issuing interim regulations to govern the filing of Correction Notices of Intent to Enforce a Restored Copyright under section 104A of the copyright law, as amended by the Uruguay Round Agreements Act. The effect of the interim regulation is to establish procedures for the correction of errors in previously filed Notices of Intent to Enforce a Restored Copyright and to provide a suggested format for submitting such information.

**DATES:** This interim regulation is effective October 28, 1997. Comments should be in writing and received on or before November 12, 1997.

**ADDRESSES:** If delivered by hand, an original and ten (10) copies of comments should be delivered to: Library of Congress, Office of the General Counsel, Copyright Office, James Madison Memorial Building, Room LM–403, First and Independence Avenue, SE., Washington, DC 20540. If sent by mail, an original and ten (10) copies of comments should be addressed to: David Carson, General Counsel, Copyright GC/I&R, PO Box 70400, Southwest Station, Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:** Charlotte Douglass, Principal Legal Advisor to the General Counsel, Copyright GC/I&R, PO Box 70400, Southwest Station, Washington, DC 20024. Telephone: (202) 707–8380. Telefax: (202) 707–8366.

**SUPPLEMENTARY INFORMATION:**

### Background

On December 8, 1994, President Clinton signed the ''Uruguay Round Agreements Act'' (URAA), Pub. L. 103–465, 108 Stat. 4809. The URAA restored copyright in certain foreign works from any country that, from January 1, 1996, forward, is a member of the Berne Convention for the Protection of Literary and Artistic Works, a member of the World Trade Organization (WTO), or subject to a Presidential Proclamation determining eligibility. 60 FR 7793 (Feb. 9, 1995); Proclamation No. 6780, 60 FR 15845 (Mar. 27, 1995). Nationals of such countries have copyright automatically restored in their works effective on the first date the particular source country becomes a country in any of the above-listed three categories. However, to be restored, works must meet certain other requirements. Such works must:

(1) Not be in the public domain in its source country through expiration of the term of protection;

(2) Be in the public domain in the United States due to noncompliance with formalities imposed at any time by United States copyright law, lack of subject matter protection in the case of sound recordings fixed before February 15, 1972, or lack of national eligibility;

(3) Have at least one author or rightholder who was, at the time the work was created, a national or domiciliary of an eligible country;

(4) If published, be first published in an eligible country and not published in the United States during the 30-day period following publication in such eligible country.

Notwithstanding the fact that the work meets the above requirements, any work ever owned or administered by the Alien Property Custodian and in which the restored copyright would be owned by a government or instrumentality thereof, is not a restored work. 17 U.S.C. 104A(a)(2).

Although copyright restoration is automatic for eligible works, a copyright owner's enforcement of its copyright against a reliance party is subject to notice to the reliance party and a waiting period. Reliance parties, in general, are persons who obtained copies of the works or were already using the works before the URAA was enacted (Dec. 8, 1994). 17 U.S.C. 104A(h)(4). Specifically, a reliance party is any person who:

(A) With respect to a particular work, engages in acts, before the source country of that work becomes an eligible country, which would have violated section 106 if the restored work had been subject to copyright protection, and who, after the source country becomes an eligible country, continues to engage in such acts;

(B) Before the source country of a particular work becomes an eligible country, makes or acquires 1 or more copies or phonorecords of that work; or

(C) As the result of the sale or other disposition of a derivative work covered under subsection (d)(3), or significant assets of a person described in subparagraph (A) or (B), is a successor, assignee, or licensee of that person.

*Id*.

The copyright owner must file with the Copyright Office a Notice of Intent to Enforce (NIE) its restored copyright or must individually serve such notice on a reliance party and must wait a period of twelve months before enforcing a restored copyright against a reliance party. A reliance party may be found liable for infringement beginning twelve months after **Federal Register** publication of the Notice of Intent to Enforce the copyright in the restored work or twelve months after a notice has been individually served on the reliance party, whichever is earlier. 17 U.S.C. 104A(d)(2). Thus, the reliance party receives a 12 month grace period during which it may use the restored work without paying licensing fees or securing permission for such use from the restored copyright owner. Id., The Uruguay Round Trade Agreements, Text of Agreements, Implementing Bill, Statement of Administrative Action, and Required Supporting Statements, H.R. Doc. No. 316, 103d Cong., 2d Sess. 324 (1994).

NIEs filed in the Copyright Office receive the benefit of constructive notice; that is, all persons are deemed to have notice of the NIE upon the Copyright Office's publication in the **Federal Register** of an NIE for a restored work. Cf. 17 U.S.C. 104A(c). Thus, the **Federal Register** publication begins the 12-month grace period concerning a particular restored work for all reliance parties, whereas the individually served NIE begins the 12-month period for only those reliance parties served, and any other reliance party with actual knowledge of such service and the contents of the notice.

Recording NIEs and publishing in the **Federal Register** the NIE titles and owners of restored copyright is part of the Copyright Office responsibilities pursuant to the URAA. 17 U.S.C. 104A(e)(1)(B). Regulations have been issued for such filings as well as special regulations for registration of claims to copyright under the URAA. 60 FR 50414 (Sept. 29, 1995).

As part of the Office's responsibility regarding NIEs, the Office has proposed rules for recording corrections to NIEs, both those NIEs containing major errors and those containing minor errors. The URAA allows a party who has filed an NIE with the Copyright Office to correct minor errors or omissions by further notice at any time after the original NIE is filed. 17 U.S.C. 104A(e)(1)(A)(iii). The procedures and fees for filing a correction to an NIE are essentially the same as those for filing an original NIE, except that the party making the correction should refer, on the corrected NIE, to the previous NIE's volume and document number in the Copyright Office Documents Records, if known. For purposes of determining the appropriate filing period, the Office will regard NIEs correcting major errors as new NIEs. Such NIEs must, therefore, be filed within the initial two year period of eligibility to be accepted as timely.

## I. Proposed Rule To Establish Correction Notices of Intent To Enforce

On July 30, 1997, the Office proposed regulations to govern the filing of Correction Notices of Intent to Enforce a Restored Copyright (Correction Notices or Correction NIEs). This rule proposed procedures to correct major and minor errors and provided a format which the Office suggested for submitting Correction Notices. The procedures (1) detailed who may file a Correction Notice, (2) distinguished between major and minor error, (3) explained that multiple NIEs could be submitted for the same work where the work had multiple owners and (4) noted that while NIEs could be withdrawn within a short time after filing, the Office will not cancel a recorded NIE.

## II. Comment

The Office received one comment in response to the publication of its proposed rule, from the Motion Picture Association of America (MPAA). This organization pointed out what it considered an inherent ambiguity in the URAA provision for minor errors but not other errors, in that sec. 104A(e)A(ii) of Title 17 permits the correction of minor errors at any time, even after the 24-month filing period, thereby leaving open the consideration of whether and when other errors may be corrected, and what effect such errors may have. One potential effect relates to when infringement remedies may be awarded against reliance parties. Under the URAA, sec. 104A(d)(2), such parties' continued use of a restored copyright after a 12-month period following the publication in the **Federal Register** of the title and owner of a restored work as listed in an NIE is subject to infringement remedies. The MPAA suggested that the Office provide by regulation that infringement remedies are available only after publication of Correction NIEs.

## III. Response

The Office addresses this comment regarding the ''inherent ambiguity'' of the URAA provision for correction of minor errors by looking to what appears to be Congress' underlying intent—to shield the public from prejudicial errors, i.e., those errors which would impede efforts by members of the public to ascertain the possible restored status of a work while assisting the NIE filer in the creation of an improved and corrected public record where a harmless error had been made. See 17 U.S.C. 104A(e)(3). While the Office has no statutory authority to establish the date on which infringement remedies are available, the distinguishing of major and minor errors facilitates the administration of NIEs where errors in an originally filed NIE may be of such a substantial nature that the initial NIE does not adequately and reasonably identify the restored work. Further, an administrative procedure recognizing the distinction between an error which would not impede the public's locating within Copyright Office records information for a given restored work and an error in an NIE which would prevent the public from being informed of the restored status for a particular work allows for a more reliable and useful public record and may possibly facilitate judicial determination of when adequate notice concerning a restored work occurred.

The Office concludes that major errors are those which pertain to the statutorily required information in the Copyright Office NIE filings: name of the copyright owner or rightholder, title of the work (but not the translation, if any) and the written agency relationship. Where the Office determines an error to be major, a Correction NIE must be filed within the two year period of eligibility. NIE filings

with the Office are voluntary. In the absence of a timely filing in the Office, the URAA allows a copyright owner of a restored work to serve an individual notice on a reliance party at any time after the date of restoration of the restored copyright to trigger a reliance party's 12-month period to use the restored work within the terms of the statute. 17 U.S.C. 104A(e)(2).

Based on the foregoing discussion, these interim regulations are essentially unchanged, except for minor technical amendments.

## IV. Procedures for Correction Notices of Intent to Enforce

### *A. Who May File a Correction Notice of Intent To Enforce (Correction NIE)*

Correction NIEs may be filed by or on behalf of the same copyright owner or rightholder who filed the original NIE. The ''same copyright owner'' includes successors in interest.

A certification by a third party is not sufficient to authorize a correction of an earlier NIE recorded in the name of another party/copyright owner, unless that third party is also the authorized agent of the copyright owner in whose name the original NIE was recorded. An authorized agent may file a Correction NIE whether or not that agent filed the original NIE.

### *B. Definition of Major and Minor Error*

The Copyright Office concludes that major errors, not defined or referenced within the statutory provisions, may be corrected only within the two-year period of eligibility for initially filing NIEs. Minor errors may be corrected at any time under the URAA provisions. (17 U.S.C. 104A(e), as amended).

The Office has determined that major errors are errors concerning the following NIE statutory requirements: the name of the copyright owner or rightholder; the title of the work (as opposed to its translation, if any); and a written agency relationship, if applicable. The Office considers these items of information to be basic identifiers crucial to the effectiveness of adequately informing the public of the existence and ownership of a particular work which is subject to a Notice of Intent to Enforce. The title of a work and the identity of the rights owner in the work, including correct information regarding an agent of the rights owner, if an agency relationship existed, must be present in the Copyright Office NIE records in order for the NIE filer to meet the requirements of the statute and to allow the public through a reasonable search to locate the essential information within Office NIE records about a given work restored to copyright under the URAA. Where the original NIE did not adequately identify the owner of the restored work, the title of the restored work or the agency relationship, the Office will refuse to record a Correction NIE that is submitted after the two-year period following a work's restoration to copyright protection.

Adequate identification of a restored work means that accurate and sufficient information concerning the three statutorily required items of owner identity, title, and agency relationship, if any, is present in the original NIE. The necessary accuracy and sufficiency of information for the original NIE includes, but is not limited to, completeness of the information, accurate spelling of names and titles, and correct sequencing of wording within names and titles so that a reasonable search of the NIE records will reveal the work in question. The following are examples where original NIEs contain information which would not result in a reasonable search revealing the actual, correct title or owner identity for the restored work:

Title in original NIE: Robert Meets the Green Rabbit Again
Title in Correction NIE: Here We Go Again—The Green Rabbit and Robert
Title in original NIE: Now Are the Times That Try Men's Souls
Title in Correction NIE: Trying Times for Mankind
Owner in original NIE: Kathy and Lori Film Production, Inc.
Owner in Correction NIE: Kathy Lorenzo and Lori Lorenzo

Where the two-year period has expired and where there is doubt as to whether an error is major or minor, i.e., whether the erroneous NIE is such that it would fail to inform members of the public doing a reasonable search of the Copyright Office records of the existence of a work that is subject to a Notice of Intent to Enforce, the Office will correspond with the filer concerning the doubt and, if appropriate, may resolve the doubt in favor of the filer and record the Correction NIE .

Because the regulations of the Copyright Office allow the recordation of any document pertaining to a copyright, in instances where the Office refuses the recordation of a Correction NIE because the two-year period of eligibility for initial filing of an NIE has passed, a party may record any document, including one concerning rights restored under the URAA for a given work, but may not designate the document on its face to be a Notice of Intent to Enforce or a Correction Notice of Intent to Enforce. *See* 37 CFR 201.4 for Copyright Office regulations on recordation of transfers and other documents. All documents, including NIEs and Correction NIEs, submitted for recordation with the Office are found within the same bibliographic database and a reasonable search by title or owner should reveal *all* recordations filed with the Office concerning the same title or owner identity.

### *C. Designation for a Correction Notice of Intent to Enforce*

A Correction NIE must be clearly indicated as such, i.e., the document filed should bear the title ''Correction Notice of Intent To Enforce,'' or ''Correction NIE.'' It must also specify the volume and document number for the recordation of the original NIE. This will enable the Office to record the correction with the appropriate cross-reference to the volume and document number of the original NIE.

### *D. Format Information for Correction NIEs*

The suggested format for filing Correction NIEs generally follows the outline of the suggested format for the original filing. This is included as Appendix A below.

The format will be made available over the Internet from where it can be downloaded for use. Where a party wishes to correct in the same filing NIEs for many titles, he or she can adapt the suggested format to allow more space for titles. Use of the format enables the filer to furnish information prescribed by the original NIE regulation in orderly form.

When information (either required or optional) has been correctly given on the original NIE, the Correction NIE need not repeat that information. Filers should include information in the Correction NIE, however, that was omitted from the previous NIE which will help identify the restored work(s) involved.

Correction NIEs must be in English, except for the original title, and either typed or printed by hand legibly in dark, preferably black, ink. They should be on 8½″ by 11″ white paper of good quality, with at least a 1″ (or 3 cm) margin.

### *E. Fees*

The fee for a correction is the same as that for an initial NIE: for one work, the fee is thirty U.S. Dollars; for multiple works that meet the conditions for being filed on the same NIE, the fee is thirty U.S. Dollars for the first work, plus one dollar for each additional work. For NIE

filings, including corrections, see 37 CFR 201.33(e) for fee information.

The filing fee partially reimburses the Office for its processing costs; the Office, therefore, does not refund fees for errors made by filers in NIEs.

### V. Multiple NIEs for the Same Work and Correction Cross-References

When rights in a restored work are owned by several different parties, multiple NIEs for the same work may be submitted. For example, one person may own the exclusive right of reproduction and public distribution and another the exclusive right of public performance. When a work has multiple rights owners, each owner must file a separate NIE subject to the requirements for initial filing within two years of eligibility to receive the benefit of NIE filing. In the instance of multiple owners of rights in a single work, if a party is acting on behalf of an earlier owner of record in an NIE and purporting to correct that earlier NIE, the Office points out that only the NIE record in the name of that particular earlier owner will be cross-referenced. Nevertheless, all NIE records for a given title will be easily retrievable as a group; if the works as recorded bear the same title, the NIE records would appear together in any title search of online records.

### VI. Cancellations and Withdrawals

The Office will not cancel a recordation of an NIE unless the recordation fee is uncollectible. While the recordation of NIEs may not, with the exception of an uncollectible fee, be canceled (i.e., expunged from the record), a request to record an NIE may be withdrawn if the request to withdraw is received before the record of the NIE has been made available to the public through the Internet. In order to withdraw an NIE, the filer must contact the Documents Unit of the Copyright Office before the online record (Copyright Office Publication and Interactive Cataloging System (COPICS)) has been made publicly available. If the Office has prepared the record for a work that is later withdrawn, it will not refund the fee.

### VII. Publication of Additional NIE List

Under the URAA, the Office must publish the **Federal Register** list of NIEs processed by the Office every four months. 17 U.S.C. 104A(e)(1)(B)(i). Accordingly, lists have been published beginning on May 1, 1996. (61 FR 19372 (May 1, 1996); 61 FR 46134 (Aug. 30, 1996); 61 FR 68454 (Dec. 27, 1996); 62 FR 20211 (April 25, 1997) and 62 FR 44842 (Aug. 22, 1997)). The Office will publish its next list on December 19, 1997. This list will include NIEs received and processed in the Office through December 5, 1997. The final **Federal Register** list for works from countries that became eligible to file on January 1, 1996, is scheduled to be published on January 30, 1998. Cf. 17 U.S.C. 104A(e)(1)(B)(ii). This will include NIEs previously received in the Office but unprocessed by December 5, 1997, and NIEs received between December 5, 1997, and December 31, 1997, inclusive.

Correction NIEs for major errors and new NIEs from source countries that became eligible to file on January 1, 1996, must be postmarked by December 31, 1997, to be accepted for January **Federal Register** publication. Correction NIEs for minor errors are acceptable at any time following eligibility, but the Office will not publish such minor corrections in the **Federal Register**.

### List of Subjects in 37 CFR Part 201

Cable television, Copyright, Jukeboxes, Literary works, Satellites.

### Interim Regulation

In consideration of the foregoing, the Copyright Office amends 37 CFR part 201 in the manner set forth below:

## PART 201—GENERAL PROVISIONS

1. The authority citation for part 201 is revised to read as follows:

**Authority:** 17 U.S.C. 702.

2. Section 201.34 is added to read as follows:

### § 201.34 Procedures for filing Correction Notices of Intent to Enforce a Copyright Restored under the Uruguay Round Agreements Act.

(a) *General.* This section prescribes the procedures for submission of corrections of Notices of Intent to Enforce a Copyright (NIEs) Restored under the Uruguay Round Agreements Act of December 8, 1994, as required by 17 U.S.C. 104A(e), as amended by Pub. L. 103–465, 108 Stat. 4809, 4976 (1994).

(b) *Definitions.* For purposes of this section, the following definitions apply.

(1) *Major error.* A major error in filing a Notice of Intent to Enforce a Copyright Restored under the Uruguay Round Agreements Act is an error in the name of the copyright owner or rightholder, or in the title of the work (as opposed to its translation, if any) where such error fails to adequately identify the restored work or its owner through a reasonable search of the Copyright Office NIE records. Omission of, or incorrect information regarding, a written agency relationship also constitutes a major error.

(2) *Minor error.* A minor error in filing a Notice of Intent to Enforce a Copyright Restored under the Uruguay Round Agreements Act is any error that is not a major error.

(3) *Restored work.* For the definition of works restored under the URAA, *see* 37 CFR 201.33.

(c) *Forms.* The Copyright Office does not provide forms for Correction Notices of Intent to Enforce filed with the Copyright Office. It requests that filers of such Correction NIEs follow the format set out in Appendix A of this section and give all information listed in paragraph (d) of this section. Correction NIEs must be in English, and should be typed or legibly printed by hand in dark, preferably black ink, on 8½″ by 11″ white paper of good quality with at least a 1″ (or three cm) margin.

(d) *Requirements for Correction Notice of Intent to Enforce a Copyright Restored under the Uruguay Round Agreements Act.* (1) A correction for a Notice of Intent to Enforce should be clearly designated as a ''Correction Notice of Intent to Enforce'' or ''Correction NIE.''

(2) Correction Notices of Intent to Enforce should be sent to the following address: URAA/GATT, NIEs and Registrations, PO Box 70400, Southwest Station, Washington, DC 20024, USA.

(3) A Correction NIE shall contain the following information:

(i) The volume and document number of the previous NIE which is to be corrected;

(ii) The title of the work as it appears on the previous NIE, including alternative titles, if they appear;

(iii) The English translation of the title, if any, as it appears on the previous NIE;

(iv) A statement of the erroneous information as it appears on the previous NIE;

(v) A statement of the correct information as it should have appeared and an optional explanation of its correction; or

(vi) A statement of the information to be added. This includes optional information such as:

(A) Type of work;

(B) Rights owned by the party on whose behalf the Correction Notice is filed;

(C) Name of author;

(D) Source country;

(E) Year of publication;

(F) Alternative titles;

(G) An optional explanation of the added information.

(vii) The name and address:

(A) To which correspondence concerning the document should be sent; and

(B) To which the acknowledgment of the recordation of the Correction NIE should be mailed; and

(viii) A certification. The certification shall consist of:

(A) A statement that, for each of the works named above, the person signing the Correction NIE is the copyright owner, or the owner of an exclusive right, or the owner's authorized agent, and that the information is correct to the best of that person's knowledge;

(B) The typed or printed name of the person whose signature appears;

(C) The signature and date of signature; and

(D) The telephone and telefax number at which the owner, rightholder, or agent thereof can be reached.

(4) A Correction NIE may cover multiple works in multiple NIE documents for one fee provided that: each work is identified by title; all the works are by the same author; all the works are owned by the same copyright owner or owner of an exclusive right. In the case of Correction NIEs, the notice must separately designate each title to be corrected, noting the incorrect information as it appeared on the previously filed NIE, as well as the corrected information. A single notice covering multiple titles need bear only a single certification.

(5) Copies, phonorecords or supporting documents cannot be made part of the record of a Correction NIE and should not be submitted with the document.

(6) Time for Submitting Correction NIEs.

(i) *Major errors.* The Copyright Office will accept a Correction NIE for a major error concerning a restored work during the 24-month period beginning on the date of restoration of the work, as provided for original NIEs in section 104A(d)(2)(A) of title 17.

(ii) *Minor errors.* The Office will accept a Correction NIE for a minor error or omission concerning a restored work at any time after the original NIE has been filed, as provided in section 104A(e)(1)(A)(iii) of title 17.

(e) *Fee.*—(1) *Amount.* The filing fee for recording Correction NIEs is 30 U.S. dollars for each Correction Notice covering one work. For single Correction NIEs covering multiple works, that is, for works by the same author and owned by the same copyright owner or owner of an exclusive right, the fee is 30 U.S. dollars, plus one dollar for each additional work covered beyond the first designated work.

(2) *Method of payment.* See 37 CFR 201.33(e)(1),(2).

(f) *Public online access.* Information contained in the Correction Notice of Intent to Enforce is available online in the Copyright Office History Documents (COHD) file through the Library of Congress electronic information system, available through the Internet. This file is available from computer terminals located in the Copyright Office itself or from terminals located in other parts of the Library of Congress through the Library of Congress Information System (LOCIS). Alternative ways to connect through Internet are the World Wide Web (WWW), using the Copyright Office Home Page at: http:/www.loc.gov/copyright; directly to LOCIS through the telnet address at locis.loc.gov; or the Library of Congress through gopher LC MARVEL and WWW which are available 24 hours a day. LOCIS is available 24 hours a day, Monday through Friday. For the purpose of researching the full Office record of Correction NIEs on the Internet, the Office has made online searching instructions accessible through the Copyright Office Home Page. Researchers can access them through the Library of Congress Home Page on the World Wide Web by selecting the copyright link. Select the menu item ''Copyright Office Records'' and/or ''URAA, GATT Amends U.S. law.'' Images of the complete Correction NIEs as filed will be stored on optical disk and will be available from the Copyright Office.

## Appendix A to § 201.34—Correction Notice of Intent To Enforce

### Correction of Notice of Intent To Enforce

1. Name of Copyright Owner (or owner of exclusive right) If this correction notice is to cover multiple works, the author and the rights owner must be the same for all works covered by the notice.)

_____

2. Title(s) (or brief description)
   (a) Work No. 1—_____
   Volume and Document Number: _____
   English Translation: _____
   (b) Work No. 2 (if applicable)—_____
   Volume and Document Number: _____
   English Translation: _____
   (c) Work No. 3 (if applicable)—_____
   Volume and Document Number: _____
   English Translation: _____
   (d) Work No. 4 (if applicable)—_____
   Volume and Document Number: _____
   English Translation: _____
3. Statement of incorrect information on earlier NIE:

_____

4. Statement of correct (or previously omitted) information:

_____

Give the following only if incorrect or omitted on earlier NIE:

(a) Type of work _____
(b) Rights owned _____
(c) Name of author (of entire work) _____
(d) Source Country _____
(e) Year of Publication (Approximate if precise year is unknown) _____
(f) Alternative titles _____

5. Explanation of error:

_____

6. Certification and Signature: I hereby certify that for each of the work(s) listed above, I am the copyright owner, or the owner of an exclusive right, or the owner's authorized agent, the agency relationship having been constituted in a writing signed by the owner before the filing of this notice, and that the information given herein is true and correct to the best of my knowledge.

_____

Name and Address (typed or printed):

_____

Telephone/Fax:

_____

As agent for:

_____

Date and Signature:

_____

Dated: October 22, 1997.

**Marybeth Peters,**

*Register of Copyrights.*

[FR Doc. 97–28488 Filed 10–27–97; 8:45 am]

BILLING CODE 1410–30–P

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## LIBRARY OF CONGRESS

## Copyright Office

## 37 CFR Part 203

**[Docket No. 97–7]**

## Implementation of the Electronic Freedom of Information Act Amendments of 1996

**AGENCY:** Copyright Office, Library of Congress.

**ACTION:** Interim regulations with request for comments.

**SUMMARY:** The Copyright Office is issuing interim regulations regarding the Freedom of Information Act to comply with changes mandated by the Electronic Freedom of Information Act Amendments of 1996. The effect of the interim regulations is to permit public access to Office records that were created on or after October 1, 1996, in electronic format. The Office seeks comment on these interim regulations.

**EFFECTIVE DATE:** This interim regulation is effective November 1, 1997. Written comments should be received on or before November 28, 1997.

**ADDRESSES:** *By mail:* Ten copies of written comments should be addressed to David O. Carson, General Counsel, Copyright GC/I&R, P.O. Box 70400, Southwest Station, Washington, D.C. 20024. *By hand:* Ten copies of written

comments should be delivered to the Office of the General Counsel, U.S. Copyright Office, James Madison Memorial Building, Room 403, First and Independence Avenue, S.E., Washington, D.C.

**FOR FURTHER INFORMATION CONTACT:**

Marilyn J. Kretsinger, Assistant General Counsel, or Patricia L. Sinn, Senior Attorney, Copyright GC/I&R, P.O. Box 70400, Southwest Station, Washington, D.C. 20024. Telephone: (202)707–8380. Fax: (202)707–8366.

**SUPPLEMENTARY INFORMATION:**

## I. Background

The Copyright Office is adopting interim regulations to Part 203 of its regulations to implement the Electronic Freedom of Information Act Amendments of 1996 (EFOIA), Pub. L. No. 104–231, 110 Stat. 3048 (1996), which amends the Administrative Procedure Act (APA), title 5, United States Code. The Office is subject to the Freedom of Information Act (FOIA), which is part of the APA, under 17 U.S.C. 701(d). Section 701(d) provides that ''[e]xcept as provided by section 706(b) and the regulations issued thereunder, all actions taken by the Register of Copyrights under this title are subject to the provisions of the Administrative Procedure Act of June 11, 1946, as amended * * *'' Copyright Office regulations describe records and documents available for public inspection under the Copyright Act and under the FOIA. *See* 37 CFR 201.2, 203. The Copyright Office is part of the Library of Congress, a legislative agency, and is an office of public record governed in its record-keeping activities by sections of the copyright statute that designate which records are available for public inspection and search. *See* 17 U.S.C. 705, 706. Copyright Office records include deposits, registrations, indexes, recordations, and other actions taken under title 17. 17 U.S.C. 705(a). Public records maintained by the Office are the subject of most requests for information received; thus, the Office receives few actual FOIA requests that must be answered outside the realm of its normal public information services.

The FOIA, which establishes a right of access to certain federal agency records, was enacted 30 years ago, before the extensive use of computers to create and retain records in electronic formats. With the advent and widespread acceptance of new information technologies, questions arose about how electronic records should be handled under the FOIA. The EFOIA, signed into law on October 2, 1996, contains amendments that address methods required to make agency records available to the public by electronic means and in electronic formats. This interim regulation revises several provisions of the Office's FOIA regulations under 37 CFR 203 to comply with provisions of the EFOIA.

## II. Interim Amendments

### *A. Form or Format Requests*

A significant change enacted in the EFOIA is the requirement that agencies honor requests to provide records created after October 1, 1996, in specific formats, including electronic formats, so long as the records are ''readily reproducible by the agency in that form or format'' by use of reasonable efforts. EFOIA sec. 5 (codified as 5 U.S.C. 552(a)(3)(B). The Office will consider the particular set of circumstances involved with each individual FOIA request to determine whether it can reasonably comply with a request to provide a record in a particular format. Prior to this amendment, the FOIA did not place agencies under an obligation to accommodate a FOIA requester's preferences as to format. The Office is amending § 203.4(a) of its regulations to reflect EFOIA requirements by adding language to reflect that the Office will produce agency records in response to a FOIA request in either traditional paper form or, if possible, in electronic form.

### *B. Fees*

Fees currently set forth in 37 CFR 203.6 apply to the costs of duplication, review of documents, and copying of paper pages. Under 37 CFR 203.6(b)(2), the current charge of $0.45 per page for copies of Office records will be assessed for paper pages of computer printouts generated by the Office, matching the current per-page charge for copies beyond the first 15 pages, for which seven dollars is charged. These fees will be modified if the Office adjusts its fees to cover the costs of providing services. The Office will charge a requester the actual cost for provision of computer discs containing requested information. For security reasons, the Office will not use discs or other electronic storage media supplied by requesters for purposes of downloading requested information.

In addition to EFOIA adjustment, the Office is adjusting fees in 37 CFR 203.6(b)(6) regarding fees for services rendered. The time charged for an employee's computer search of records remains the actual cost of the search including the cost of operating equipment for the time directly attributable to searching for records responsive to a request, but modifies the cost of the operator/programmer's time involved in conducting a search from $10.00 per hour or fraction thereof to $20.00 per hour or fraction thereof. The Office's authority to raise discretionary fees is found in 17 U.S.C. 708(a)(10).

### *C. Time for Processing Initial FOIA Requests*

The EFOIA provides that effective October 2, 1997, agencies will have twenty working days, rather than the current ten working days, to respond to initial FOIA requests. EFOIA sec. 8(b)(codified as 5 U.S.C. 552(a)(6)(A)(i)). The Office proposes to amend § 203.4(f) of its FOIA regulations to implement this aspect of the EFOIA.

The EFOIA recognizes that in ''unusual circumstances'' agencies may need more than twenty working days to process FOIA requests. EFOIA sec. 7(b) (codified as 5 U.S.C. 552(a)(6)(B). If an extension of more than ten working days is sought, the EFOIA amendments require that an agency provide requesters with the opportunity to limit the scope of their requests to enable processing within the ten day statutory time limit for extensions, or to negotiate an alternate time frame for processing requests. *Id.* The Office proposes to amend its FOIA regulations to reflect these changes.

### *D. Expedited Processing*

The EFOIA requires agencies to promulgate through a notice and comment rulemaking regulations to consider requests for ''expedited processing'' of initial FOIA requests. EFOIA sec. 8(a) (codified as 5 U.S.C. 552(a)(6)(E)). Such requests must be granted whenever a ''compelling need'' is demonstrated by the requesting party. ''Compelling need'' is defined in the EFOIA as: (1) involving ''an imminent threat to the life or physical safety of an individual,'' or (2) in the case of a request made by ''a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity.'' EFOIA sec. 8(a) (codified as 5 U.S.C. 552(a)(6)(E)(v)). When a request for expedited processing is made, an agency must notify the requester of its decision whether or not to grant the expedited request within ten (10) calendar days. If expedited processing is granted, an agency must process the request as soon as practicable. If the request is denied, an agency must consider an appeal of such a denial. To implement the expedited processing requirements of the EFOIA amendments, the Office proposes to amend section 203.4 of our regulations

by adding that the Office will process requests granted expedited processing status ''as soon as is practicable.'' EFOIA sec. 8(a) (codified as 5 U.S.C. 552(a)(6)(E)(iii)).

*E. Electronic Reading Room*

The FOIA requires agencies to make available for inspection and copying statements of policy and interpretations not published in the **Federal Register**, and administrative staff manuals and instructions to staff that affect the public. 5 U.S.C. 552(a)(2). The Office maintains these materials in paper form in its Public Information Office. *See* 37 CFR 203.4. The EFOIA requires agencies to make available by ''computer telecommunications or * * * by other electronic means'' all reading room materials that are created on or after October 1, 1996. EFOIA sec. 4 (codified at 5 U.S.C. 552(a)(2). The statute envisions that agencies will develop both a traditional reading room and an electronic reading room. The Office proposes an interim regulation stating which materials are available on-line or in an accessible electronic format.

**List of Subjects in 37 CFR Part 203**

Freedom of Information Act, Policies and procedures.

**Interim Regulations**

In consideration of the foregoing, the Copyright Office is amending part 203 of 37 CFR, chapter II, in the manner set forth below:

## PART 203—FREEDOM OF INFORMATION ACT: POLICIES AND PROCEDURES

1. The authority citation for part 203 is amended to read as follows:

**Authority:** 17 U.S.C. 702; and 5 U.S.C. 552, as amended.

2. Section 203.3 is amended by revising paragraph (i) to read as follows:

**§ 203.3 Organization.**

* * * * *

(i) The Copyright Office maintains an ''electronic reading room'' by making available certain documents and records on its World Wide Web page and by providing access to documents that affect the public in electronic format pursuant to 5 USC 552(a)(2). Copyright Office records in machine-readable form cataloged from January 1, 1978, to the present, including registration information and recorded documents, are available on the Internet. Frequently requested Copyright Office circulars, announcements, and recently proposed as well as final regulations are available on-line. The address for the Copyright Office's home page is: http://www.loc.gov/copyright; information may also be accessed by connecting to the Library of Congress' home page on the World Wide Web. The address is: http://www.loc.gov. Other Copyright Office documents may be provided on disk when so requested.

3. Section 203.4 is amended by revising paragraph (f) and adding a new paragraph (i) to read as follows:

**§ 203.4 Methods of operation.**

* * * * *

(f) The Office will respond to all properly marked mailed requests and all personally delivered written requests for records within twenty (20) working days of receipt by the Supervisory Copyright Information Specialist. Inquiries should be mailed to: Copyright Office, GC/I&R, P.O. Box 70400 Southwest Station, Washington, D.C. 20024. If hand delivered, materials should go to: Copyright Public Information Office, LM 401, James Madison Memorial Building, Library of Congress, 101 Independence Avenue, S.E., Washington, D.C. Office hours are from 8:30 a.m. to 5:00 p.m., Monday through Friday, excluding holidays. If it is determined that an extension of time greater than ten (10) working days is necessary to respond to a request due to unusual circumstances, as defined in paragraph (i) of this section, the Supervisory Copyright Information Specialist shall so notify the requester and give the requester the opportunity to:

(1) Limit the scope of the request so that it may be processed within twenty (20) working days, or

(2) Arrange with the Office an alternative time frame for processing the request or a modified request. If a request is denied, the written notification will include the basis for the denial, names of all individuals who participated in the determination, and procedures available to appeal the determination.

* * * * *

(i) The Supervisory Copyright Information Specialist will consider requests for expedited processing of requests in cases where the requester demonstrates a compelling need for such processing. The term ''compelling need'' means:

(1) That a failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(2) With respect to a request made by a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity. Requesters for expedited processing must include in their requests a statement setting forth the basis for the claim that a ''compelling need'' exists for the requested information, certified by the requester to be true and correct to the best of his or her knowledge and belief. The Office will determine whether to grant a request for expedited processing and will notify the requester of such determination within ten (10) days of receipt of the request. If a request for expedited processing is approved, documents responsive to the request will be processed as soon as is practicable. Denials of requests for expedited processing may be appealed to the Office of the General Counsel, who will expeditiously determine any such appeal.

**§ 203.6 [Amended]**

5. Section 203.6(b)(6) is amended by revising the parenthetical at the end of the sentence to read ''(at no less than $20.00 per hour or fraction thereof).''

Dated: October 21, 1997.

**Marybeth Peters,**

*Register of Copyrights.*

[FR Doc. 97–28418 Filed 10–27–97; 8:45 am]

BILLING CODE 1410–30–P

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## LIBRARY OF CONGRESS

## Copyright Office

## 37 CFR Part 258

**[Docket No. 96–3 CARP SRA]**

## Rate Adjustment for the Satellite Carrier Compulsory License

**AGENCY:** Copyright Office, Library of Congress.

**ACTION:** Final rule and order.

**SUMMARY:** The Librarian of Congress, upon recommendation of the Register of Copyrights, is announcing the adjustment of the royalty rates for superstation and network signals under the satellite carrier compulsory license, 17 U.S.C. 119.

**EFFECTIVE DATE:** January 1, 1998.

**ADDRESSES:** The full text of the CARP's report to the Librarian of Congress is available for inspection and copying during normal business hours in the Office of the General Counsel, James Madison Memorial Building, Room LM–403, First and Independence Avenue, S.E., Washington, D.C. 20540.

**FOR FURTHER INFORMATION CONTACT:** David O. Carson, General Counsel, William J. Roberts, Jr., Senior Attorney for Compulsory Licenses, or Tanya M. Sandros, Attorney Advisor, P.O. Box

70977, Southwest Station, Washington, D.C. 20024. Telephone (202) 707–8380.

**SUPPLEMENTARY INFORMATION:**

## Recommendation of the Register of Copyrights

### I. Background

Congress passed the Satellite Home Viewer Act of 1988 to create a compulsory copyright license, codified at section 119 of the Copyright Act, for the retransmission of over-the-air television broadcast signals. 17 U.S.C. 119. Similar in many ways to the cable compulsory license enacted by Congress in 1976, the satellite carrier compulsory license permits satellite carriers to retransmit TV signals to their subscribers upon semiannual submission of royalty fees and statements of account to the Copyright Office. The royalty fees collected by the Copyright Office are deposited with the United States Treasury for subsequent distribution to copyright owners of programming retransmitted by the satellite carriers.

Section 119 identifies two types of television broadcast signals that are subject to compulsory licensing: superstations and network signals. A superstation is the signal of any commercial independent television station licensed by the Federal Communications Commission. Examples of superstations retransmitted by satellite carriers under section 119 are WTBS, Atlanta and WGN, Chicago. A network station is defined as follows:

> (A) A television broadcast station, including any translator station or terrestrial satellite station that rebroadcasts all or substantially all of the programming broadcast by a network station, that is owned or operated by, or affiliated with, one or more of the television networks in the United States which offer an interconnected program service on a regular basis for 15 or more hours per week to at least 25 of its affiliated television licensees in 10 or more States; or
>
> (B) A noncommercial educational broadcast station (as defined in section 397 of the Communications Act of 1934).[1]

17 U.S.C. 119(d)(2). Examples of network signals carried by satellite carriers are ABC, CBS, and NBC. A station of the Public Broadcasting Service (PBS) would also be considered a network signal under the statute.

Under the section 119 license, satellite carriers can retransmit any superstation they choose to any subscriber located anywhere in the United States. However, such is not the case with the retransmission of network signals. Satellite carriers may only make use of the license to retransmit a network signal to a subscriber who resides in an ''unserved household.'' An ''unserved household'' is defined as a household that:

> (A) Cannot receive through the use of a conventional outdoor rooftop receiving antenna, an over-the-air signal of grade B intensity (as defined by the Federal Communications Commission) of a primary network station affiliated with that network, and
>
> (B) Has not, within 90 days before the date on which that household subscribes, either initially or on renewal, to receive secondary transmissions by a satellite carrier of a network station affiliated with that network, subscribed to a cable system that provides the signal of a primary network station affiliated with that network.

17 U.S.C. 119(d)(10). Service of network signals to subscribers who do not reside in unserved households is an act of copyright infringement, subject to the remedies of chapter 5 of the Copyright Act, unless the carrier is able to negotiate a private agreement with copyright owners to license all the copyrighted works on those network signals.

In creating the section 119 license in 1988, Congress established different royalty rates for superstation and network signals, based upon approximations of what cable paid for such signals under the section 111 cable compulsory license. 17 U.S.C. 111. The original rate for a superstation was 12 cents per subscriber per month. The original rate for a network was 3 cents per subscriber per month. Congress, however, authorized a rate adjustment procedure to change these rates in 1992.

### II. The 1992 Rate Adjustment

At the time of passage of section 119, the Copyright Royalty Tribunal was still in existence. However, rather than invest the Tribunal with authority to adjust the section 119 rates, as was the case for all other compulsory licenses in the Copyright Act, Congress instead gave the task to an ad hoc arbitration panel assembled solely for that purpose. The Tribunal was given authority to review the decision of the arbitration panel, as is the Librarian in this proceeding, but under a different standard of review.

Congress also established a number of factors for the arbitration panel to consider in reaching its determination. The statute provided:

> In determining royalty fees under this paragraph, the Arbitration Panel shall consider the approximate average cost to a cable system for the right to secondarily transmit to the public a primary transmission made by a broadcast station, the fee established under any voluntary agreement filed with the Copyright Office in accordance with paragraph (2),[2] and the last fee proposed by the parties, before proceedings under this paragraph, for the secondary transmission of superstations or network stations for private home viewing. The fee shall also be calculated to achieve the following objectives:
>
> (i) To maximize the availability of creative works to the public.
>
> (ii) To afford the copyright owner a fair return for his or her creative work and the copyright user a fair income under existing economic conditions.
>
> (iii) To reflect the relative roles of the copyright owner and the copyright user in the product made available to the public with respect to relative creative contribution, technological contribution, capital investment, cost, risk, and contribution to the opening of new markets for creative expression and media for their communication.
>
> (iv) To minimize any disruptive impact on the structure of the industries involved and on generally prevailing industry practices.

17 U.S.C. 119(c)(3)(B) (1988).

The arbitration panel was given 60 days to reach its determination; it delivered its report to the Copyright Royalty Tribunal on March 2, 1992. The panel recommended that the royalty fee for network signals be raised from 3 cents to 6 cents per subscriber. 57 FR 19061 (May 1, 1992). For superstations, the panel recommended a two-tiered rate structure. The panel was impressed with Congress' consideration of the application of syndicated exclusivity protection on the satellite industry. With respect to cable retransmissions of broadcast signals, broadcasters may purchase exclusive rights to broadcast programming within their local market, and any cable operator importing the same programming into the broadcaster's local market is required to black it out. Congress directed the FCC in 1988 to consider adopting syndicated exclusivity rules for the satellite industry, but the Commission ultimately determined that it was not technically feasible for satellite carriers to black-out programming. See 6 FCC Rcd. 725 (1991). To make up for this technological deficiency, the panel imposed a higher royalty rate to compensate for the loss of exclusivity protection.

For superstations, if they had been retransmitted by a cable system rather than a satellite carrier and would have been subject to the FCC's syndicated exclusivity rules, the panel adopted a rate of 17.5 cents per subscriber per month. 57 FR at 19061 (1992). For

[1] This is the definition of a network signal after the 1994 amendments to section 119. The earlier definition was the same one appearing in section 111 of the Copyright Act.

[2] No such voluntary agreements were reached.

signals that would not have been subject to the syndicated exclusivity rules for cable (known as ''syndex proof'' signals), the panel adopted a rate of 14 cents per subscriber per month. *id*.

The Copyright Royalty Tribunal, reviewing the panel's decision only under a contrary to law standard, adopted the rates recommended by the arbitration panel. 57 FR 19052 (1992). The Tribunal did, however, substitute a new effective date for the rates, because it determined that the panel misapplied the statute. *Id*. at 19053 (rates effective on date of issuance of Tribunal's order, May 1, 1992, not January 1, 1993 date recommended by panel). No appeal of the Tribunal's order was taken.

## III. Satellite Home Viewer Act of 1994

The rates adopted by the Tribunal in 1992 were to last only until the end of 1994, when the section 119 license was slated to expire. However, in 1994, Congress passed the Satellite Home Viewer Act of 1994, which extended the section 119 license another 5 years. In reauthorizing the license, Congress made several changes to its provisions. Another rate adjustment—this proceeding—was scheduled to take place, and the duty of conducting the proceeding was given to a copyright arbitration royalty panel (CARP), with review by the Librarian of Congress.

The most significant change to section 119 made by the 1994 amendments, for purposes of this proceeding, was a change in the factors to be applied by the CARP to determine the new royalty rates. Rather than focus on the price paid by the cable industry for similar retransmissions, Congress required that the royalty fees for superstations and network signals represent the fair market value. 17 U.S.C. 119(c)(3)(D) (1994).

Although Congress intended to replace the statutory criteria for adjusting the royalty rates from the 1988 Act with the new ''fair market value'' standard, a scrivener's error was made in the 1994 Act. The result was that the original provisions of section 119(c)(3)(B) remained, and the new provisions inadvertently replaced the subparagraph determining those parties subject to pay the section 119 royalty fees. Certain copyright owners to this proceeding requested clarification of the statute, and the Library issued an order prior to commencement of the CARP instructing the CARP to apply only the new fair market value provisions, and to disregard the old criteria of section 119(c)(3)(B). Order in Docket No. 96–3 CARP SRA (January 6, 1997).

The royalty rates adopted in the 1992 rate adjustment were incorporated into the 1994 Act, subject to adjustment in this proceeding. The rates adopted in this Order shall remain effective until December 31, 1999, the current date for the section 119 compulsory license.

## IV. This Proceeding

Pursuant to section 119(c)(2), the Librarian of Congress initiated this proceeding with publication of a **Federal Register** notice on June 11, 1996, establishing a voluntary negotiation period and a precontroversy discovery schedule.[3] 61 FR 29573 (June 11, 1996). The schedule was vacated on September 19, 1996, at the request of certain copyright owner parties, Order in Docket No. 96–3 CARP SRA (September 19, 1996), and rescheduled on October 29, 1996. Order in Docket No. 96–3 CARP SRA (October 29, 1996). The CARP was convened on March 3, 1997.

The following parties submitted written direct cases to the CARP: (1) Joint Sports Claimants (''JSC''), representing national sports associations including Major League Baseball, the National Basketball Association, the National Hockey League, and the National Collegiate Athletic Association; (2) the Public Broadcasting Service (''PBS''); (3) the Commercial Network Claimants (''Commercial Networks''), representing the National Broadcasting Co., Inc., Capital Cities/ABC, Inc. and CBS, Inc.; (4) the Broadcaster Claimants Group (''Broadcaster Claimants Group''), representing certain commercial television stations whose signals are retransmitted by satellite carriers; (5) the Program Supplier Claimants (''Program Suppliers''), representing various copyright owners of motion pictures, television series and specials; (6) the Music Claimants (''Music Claimants''), representing the American Society of Composers, Authors and Publishers, Broadcast Music, Inc., and SESAC, Inc.; (7) the Devotional Claimants (''Devotional Claimants''), representing various copyright owners of religious programming; (8) the Satellite Broadcasting & Communications Association (''SBCA''), representing AlphaStar Television, Inc., BosCom, Inc., Consumer Satellite Systems, DirecTV, Inc., EchoStar Communications Corp., Netlink USA, PrimeStar Partners L.P., Prime Time 24 Joint Venture, Southern Satellite Systems, Inc., and Superstar Satellite Entertainment; and (9) American Sky Broadcasting L.L.C. (''ASkyB'').

[3] The voluntary negotiation period proved unsuccessful as no agreements were reached.

The CARP held oral hearings on the written cases and evidence, and oral argument on the proposed findings of fact and conclusions of law. The CARP submitted its report to the Librarian on August 29, 1997.

The CARP concluded that rates for both networks signals and superstations should be adjusted upwards to 27 cents per subscriber per month. In addition, the Panel determined that no royalty fee should be paid for the retransmission of superstations within the superstations' local markets, and that it had no authority to set a royalty rate for retransmissions of network signals within their local markets. The Panel recommended July 1, 1997, as the effective date for the new rates.

Section 802(f) of the Copyright Act provides that [w]ithin 60 days after receiving the report of a copyright arbitration royalty panel * * *, the Librarian of Congress, upon the recommendation of the Register of Copyrights shall adopt or reject the determination of the panel.'' 17 U.S.C. 802(f). Today's order of the Librarian fulfills this statutory obligation.

## V. The Librarian's Scope of Review

The Librarian of Congress has, in previous proceedings, discussed his narrow scope of review of CARP determinations. See 52 FR 6558 (February 12, 1997) (DART distribution order); 61 FR 55653 (October 26, 1996) (cable distribution order). The salient points regarding the scope of review, however, merit repeating.

The Copyright Royalty Tribunal Reform Act of 1993 created a unique system of review of a CARP's determination. Typically, an arbitrator's decision is not reviewable, but the Reform Act created two layers of review: the Librarian and the Court of Appeals for the District of Columbia Circuit. Section 802(f) directs the Librarian to either accept the decision of the CARP or reject it. If the Librarian rejects it, he must substitute his own determination ''after full examination of the record created in the arbitration proceeding.'' *Id*. If the Librarian accepts it, then the determination of the CARP has become the determination of the Librarian. In either case, through issuance of the Librarian's Order, it is his decision that will be subject to review by the Court of Appeals.

Section 802(f) of the Copyright Act directs that the Librarian shall adopt the report of the CARP ''unless the Librarian finds that the determination is arbitrary or contrary to the provisions of this title.'' Neither the Reform Act nor its legislative history indicates what is meant specifically by ''arbitrary,'' but

there is no reason to conclude that the use of the term is any different than the ''arbitrary'' standard described in the Administrative Procedure Act (APA), 5 U.S.C. 706(2)(A).

Review of the caselaw applying the APA ''arbitrary'' standard reveals six factors or circumstances under which a court is likely to find that an agency acted arbitrarily. An agency is generally considered to be arbitrary when it:

(1) Relies on factors that Congress did not intend it to consider;

(2) Fails to consider entirely an important aspect of the problem that it was solving;

(3) Offers an explanation for its decision that runs counter to the evidence presented before it;

(4) Issues a decision that is so implausible that it cannot be explained as a product of agency expertise or a difference of viewpoint;

(5) Fails to examine the data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made; and

(6) When the agency's action entails the unexplained discrimination or disparate treatment of similarly situated parties.

*Motor Vehicle Manufacturers Ass'n* v. *State Farm Mutual Insurance Co.*, 463 U.S. 29 (1983); *Celcom Comm. Corp.* v. *FCC*, 789 F.2d 67 (D.C. Cir. 1986); *Airmark Corp* v. *FAA*, 758 F2d 685 (D.C. Cir. 1985).

Given these guidelines for determining when a determination is ''arbitrary,'' prior decisions of the courts reviewing the determinations of the former Copyright Royalty Tribunal have been consulted. The decisions of the Tribunal were reviewed under the ''arbitrary and capricious'' standard of 5 U.S.C. 706(2)(A) which, as noted above, appears to be applicable to the Librarian's review of the CARP's decision.

Review of judicial decisions regarding Tribunal actions reveals a consistent theme: provided that the Tribunal adequately articulated the reasons for its decision, specific determinations were granted a relatively wide ''zone of reasonableness.'' See *National Ass'n of Broadcasters* v. *CRT*, 772 F.2d 922 (D.C. Cir. 1985); *Christian Broadcasting Network* v. *CRT*, 720 F.2d 1295 (D.C. Cir. 1983); *National Cable Television Ass'n* v. *CRT*, 689 F.2d 1077 (D.C. Cir. 1982); *Recording Industry Ass'n of America* v. *CRT*, 662 F.2d 1 (D.C. Cir. 1981). As one panel of the D.C. Circuit succinctly noted:

> To the extent that the statutory objectives determine a range of reasonable royalty rates that would serve all these objectives adequately but to differing degrees, the Tribunal is free to choose among those rates, and courts are without authority to set aside the particular rate chosen by the Tribunal if it lies within a ''zone of reasonableness.''

*Recording Industry Ass'n of America* v. *CRT*, 662 F.2d 1, 9 (D.C. Cir. 1981). Because the Librarian is reviewing the CARP decision under the same ''arbitrary'' standard used by the courts to review the Tribunal, he must be presented with a detailed rational analysis of the CARP's decision, setting forth specific findings of fact and conclusions of law. This requirement of every CARP report is confirmed by the legislative history to the Reform Act which notes that a ''clear report setting forth the panel's reasoning and findings will greatly assist the Librarian of Congress.'' H.R. Rep. No. 103–286, 103 Cong., 1st Sess. 13 (1993). Thus, to engage in reasoned decisionmaking, the CARP must ''weigh all the relevant considerations and * * * set out its conclusions in a form that permits [a determination of] whether it has exercised its responsibilities lawfully.'' *National Cable Television Ass'n* v. *CRT*, 689 F.2d 1077, 1091 (D.C. Cir. 1982). This goal cannot be reached by ''attempt[ing] to distinguished apparently inconsistent awards with simple, undifferentiated allusions to a 10,000 page record.'' *Christian Broadcasting Network, Inc.* v. *CRT*, 720 F.2d 1295, 1319 (D.C. Cir. 1983).

It is the task of the Register to review the report and make her recommendation to the Librarian as to whether it is arbitrary or contrary to the provisions of the Copyright Act and, if so, whether, and in what manner, the Librarian should substitute his own determination.

## VI. Review of the CARP Report

Section 251.55(a) of the rules provides that ''[a]ny party to the proceeding may file with the Librarian of Congress a petition to modify or set aside the determination of a Copyright Arbitration Royalty Panel within 14 days of the Librarian's receipt of the panel's report of its determination. 37 CFR 251.55(a). Replies to petitions to modify are due 14 days after the filing of the petitions. 37 CFR 251.55(b).

The following parties filed petitions to modify: SBCA, EchoStar Communications Corp. (''EchoStar''), and commercial Networks. Replies were filed by JSC, Broadcaster Claimants Group, PBS, Program Suppliers, Commercial Networks, Music Claimants and Devotional Claimants (collectively, ''Copyright Owners''), PBS, JSC and Broadcaster Claimants Group (collective, ''Certain Copyright Owners''), and EchoStar.

Satellite carriers oppose the decision of the CARP, while copyright owners are generally supportive of it. SBCA offers numerous reasons why, in its view, the Panel's decision is arbitrary and contrary to law. EchoStar confines its comments to the Panel's decision not to establish a royalty rate for the local retransmission of network signals by satellite carriers, and Commercial Networks request a ''clarification'' of the Panel's ruling in order to construe it to mean that the 27 cent fee for network signals applies to any local retransmission of network stations to subscribers in unserved households. Certain Copyright Owners challenge EchoStar's standing to file a § 251.55 petition to modify in this proceeding.

Section 251.55 of the rules assists the Register of Copyrights in making her recommendation to the Librarian, and the Librarian in conducting his review of the CARP's decision by allowing the parties to the proceeding to raise specific objections to a CARP's determination. As required by section 802(f) of the Copyright Act, if the Librarian determines that the Panel in this proceeding has acted arbitrarily or contrary to the provisions of the Copyright Act, he must ''after full examination of the record created in the arbitration proceeding, issue an order setting the royalty fee * * *.'' 17 U.S.C. 802(f).

## VII. Review and Recommendation of the Register

As discussed above, the parties to this proceeding submitted petitions to the Librarian to modify the Panel's determination based on their assertions that the Panel acted arbitrarily or contrary to the applicable provisions of the Copyright Act. These petitions have assisted the Register in identifying what evidence and issues in this large proceeding, in the eyes of the petitioners, are areas where the Panel may have acted improperly, thereby requiring the Librarian to substitute his own determination. The law gives the Register the responsibility to make recommendations to the Librarian regarding the Panel's determination, 17 U.S.C. 802(f), and in so doing she must conduct a thorough review.

After reviewing the Panel's report and the record in this proceeding, the Register has determined that there are 6 primary aspects of the Panel's decision that warrant detailed discussion and analysis:

(1) Whether the Panel correctly interpreted and applied the statutory standard for determining royalty fees;

(2) Whether the Panel acted arbitrarily in adopting the license fees paid by cable networks as the benchmark for determining section 119 fees;

(3) Whether the Panel should have made certain adjustments in the benchmark rates it adopted;

(4) Whether it was permissible for the Panel to adopt the same rate for superstations and network signals;

(5) Whether the Panel correctly declined to adopt a royalty rate for local retransmission of network signals by satellite carriers; and

(6) Whether the Panel supplied the appropriate effective date for the newly established royalty fees.

SBCA has made additional arguments in its petition to modify as to why the Panel's decision should be set aside. These arguments, which primarily involve evaluation of the evidence and allege deficiencies in the discovery rules for CARP proceedings, are addressed at the end of this section.

*A. Determination of Fair Market Value*

1. Action of the Panel

A fundamental dispute between satellite carriers and copyright owners in this proceeding is the meaning of the term ''fair market value'' as used in section 119(c)(3)(D) of the Copyright Act. That section provides: [4]

In determining royalty fees under this paragraph, the Copyright Arbitration Panel shall establish fees for the retransmission of network stations and superstations that most clearly represent the fair market value of secondary transmissions. In determining the fair market value, the Panel shall base its decision on economic, competitive, and programming information presented by the parties, including—

(i) The competitive environment in which such programming is distributed, the cost for similar signals in similar private and compulsory license marketplaces, and any special features and conditions of the retransmission marketplace;

(ii) The economic impact of such fees on copyright owners and satellite carriers; and

(iii) The impact on the continued availability of secondary transmissions to the public.

17 U.S.C. 119(c)(3)(D).

The Panel examined this provision, and the legislative history, and determined that fair market value meant the prize that would be negotiated in a free market setting as compensation for the satellite carriers' right to retransmit network and superstation signals containing the copyright owners' copyrighted programming. The Panel stated that:

[T]he language, structure, and legislative history of the 1994 amendments to section 119 suggest the Panel is directed to determine actual *fair market value* and ''in determining the fair market value * * * base its decision * * *'' upon the non-exhaustive list of *considerations*. We interpret the phrase ''base its decision'' to require the Panel to *consider* each enumerated type of information but, the weight to be accorded each consideration must necessarily depend upon the quality and quantity of the evidence adduced and *its relative significance to a determination of actual fair market value*. All evidence falling within the enumerated types of information must be considered but the evidence which is more probative of *fair market value* must be accorded greater weight than less probative evidence * * *. The Panel agrees that the fair market value rate is that which most closely approximates the rate that would be negotiated in a free market between a willing buyer and a willing seller.

Panel Report at 17 (emphasis in original).

2. Arguments of the Parties

SBCA asserts that the Panel misapprehended the meaning of ''fair market value,'' and that it should have determined the section 119 fees in accordance with what cable operators pay for distant signals under the section 111 cable compulsory license. SBCA Petition to Modify at 12. ''Fair market value is a Congressionally defined term, and thus cannot be considered under the 'traditional' sense, as urged by the [Copyright] Owners.'' *Id.* at 14. SBCA cites certain 1994 floor statements at length as evidence that Congress intended that section 119 royalty rates be set on a parity with cable rates.

DeConcini: Copyright license parity with cable is the central feature of the fair market standard articulated in this legislation. The inclusion of specific guidance to the arbitration panel to take into consideration the competitive environment in which satellite programming is distributed is essential to ensure that satellite carriers are not required to pay higher royalty fees than cable operators * * * I am confident that the arbitration panel will take steps to ensure that the royalty fee paid by satellite carriers are on par with those paid by cable operators. The guiding criteria for the arbitration panel to establish fair market value in this legislation will accomplish that objective.

* * * The fact that the Senate agrees with the House on this compromise language is due to the criteria that defines fair market value in the bill. I have long opposed the imposition of royalty fees based simply on the mechanical application of some conceptual fair market value formula * * * The arbitration panel will take steps to ensure that the royalty fees paid by satellite carriers are on par to those paid by cable operators. The guiding criteria for the arbitration panel to establish fair market value will accomplish this objective.

140 Cong. Rec. S14105, 14106 (daily ed. Oct. 4, 1994).

Brooks: In the hard-fought compromise reached on this bill, the factors to be considered under the bill's ''fair market value'' determination have been made more specific. I would note that in determining fair market value, we intend that the copyright arbitration panel consider all the factors raised by the parties, including cable rates.

140 Cong. Rec. H9270 (daily ed. Sept. 20, 1994).

Hughes: [L]egislation contemplates that the panel will look to the competitive environment in which section 119 retransmissions are distributed as well as the costs of distribution of similar signals in similar private and compulsory license marketplaces, including the cable copyright fees under section 111. This will help ensure that there is vigorous competition and diversity in the video programming distribution industry.

140 Cong. Rec. H9271 (daily ed. Sept. 20, 1994).

Synar: I am also hopeful that any fee resulting from the fair market value standard does not disadvantage the delivery of satellite transmissions vis-a-vis the delivery of cable retransmission under the section 111 compulsory license * * * It is my hope that the fees set for satellite retransmissions under the fair market value standard will, among other things, reflect the competitive environment in which those retransmissions are distributed. There is little question that Congress would like to ensure that there is vigorous competition and diversity in the distribution of video programming and the determination of fair market value fees should reflect that intent.

140 Cong. Rec. H9272 (daily ed. Sept. 20, 1994).

According to SBCA, these floor statements provide clear Congressional direction that the royalty fees for section 119 are to be either identical or substantially similar to those paid by cable operators under section111. SBCA provided testimony demonstrating that cable operators pay 9.8 cents per subscriber per month for superstations, and 2.45 cents per subscriber per month for network signals, and submits that the Librarian should adopt these rates. SBCA Petition to Modify at 18.

Copyright Owners contend that the Panel acted correctly in attributing the plain meaning to the term ''fair market value,'' and properly rejected SBCA's position that the rates paid by cable under section 111 is the governing factor in determining fair market value. Copyright Owners Reply at 12. Copyright Owners' note further that even one of SBCA's own expert witnesses, Mr. Harry Shooshan, conceded at the hearing that Congress intended to accord the conventional meaning to ''fair market value.'' *Id.*

[4] As discussed above, section 119(c)(3)(D) is the appropriate statutory provision governing the adjustment of royalty rates. Section 119(c)(3)(B), which also prescribes royalty adjustment factors, was inadvertently left in the statute after the 1994 amendments.

Copyright Owners also submit that portions of floor statements delivered at the time of passage of the 1994 Satellite Home Viewer Act are not proper legislative history and must be given little, if any, weight. *Id.* at 14–15 (citing *Overseas Educ. Ass'n, Inc.* v. *FLRA,* 876 F.2d 960 (D.C. Cir. 1989); *In the Matter of Sinclair,* 870 F.2d 1340 (7th Cir. 1989)). Rather, the text of the statute is the principle source for determining its meaning. *Id.* at 15 (citing *West Virginia Hosp.* v. *Casey,* 499 U.S. 83 (1991).

3. Recommendation of the Register

The Panel determined that the term ''fair market value'' should be accorded its plain meaning—i.e., the price a willing buyer and a willing seller would negotiate in a free marketplace—and that the economic, competitive, and programming information presented by the parties provided the evidence to determine what fair market value royalty rates would be under the satellite carrier compulsory license. The Register concludes that this decision is not arbitrary, nor is it contrary to law.

Both SBCA and Copyright Owners contend that the meaning of ''fair market value'' is a matter of statutory interpretation. Moreover, it is a well-established principle that, in interpreting the meaning of a statute, the language of the law is the best evidence of its meaning. Sutherland Stat. Const. § 46.01 (5th Ed.).

The express words of the statute charge the Panel with determining the fair market value of retransmitted broadcast signals by satellite carriers. *Id.* (plain meaning of the statute governs its interpretation). The Panel determined that ''fair market value'' meant the price that would be negotiated between a willing buyer and a willing seller in a free marketplace. Panel Report at 17. The Register determines that this is not an arbitrary interpretation of the meaning of ''fair market value,'' nor is it contrary to law. See Black's Law Dictionary 537 (5th Ed. 1989) (definition of ''fair market value'').

In the 1994 amendments Congress stated that ''[i]n determining the fair market value, the Panel shall base its decision on economic, competitive, and programming information presented by the parties * * *'' 119 U.S.C. 119(c)(3)(d). Congress then included in that amendment a nonexhaustive list of the types of ''economic, competitive, and programming information'' that the Panel must consider in fashioning royalty rates that represent fair market value. That the list is nonexhaustive is significant, for there may be other types of information presented by the parties that, while not falling within one of the enumerated categories, is nevertheless relevant to the issue of what the fair market value royalty rates should be. The Panel would be responsible for considering this type of information as well, if it were relevant to determining fair market value.

The Register does not interpret the enumerated categories of ''economic, competitive, and programming information'' (for example, costs in similar private and compulsory license marketplaces) as establishing criteria that define the meaning of ''fair market value.'' To do so would, in the Register's view, run contrary to the plain meaning of the statute. Sutherland Stat. Const. § 47.07 (5th Ed.). Likewise, the Register does not see any support for the argument that one of the enumerated categories of information, such as the compulsory license fee paid by cable under 17 U.S.C. 111, must be accorded more weight than another. The House Committee Report to the 1994 amendments makes it clear that this should not be the case. See H.R. Rep. No. 703, 103d Cong., 2d Sess. 10 (1994) (''In order to aid the panel, the Committee adopted an amendment offered by Mr. Hughes directing the panel to consider economic, competitive, and programming information presented by the parties as well as the competitive environment in which such programming is distributed. This would, of course, include cable rates, but those rates are not to be a benchmark for setting rates under section 119; they are only one potentially [sic] piece of evidence in reaching the objective fair market value.''). The Register, therefore, determines that the Panel did not act arbitrarily or contrary to law in determining the meaning of fair market value.

Although the Panel determined that its plain meaning of fair market value controlled their interpretation, the Panel nevertheless consulted the legislative history to the 1994 amendments and concluded that ''[w]e find no support for the proposition that Congress did not mean what it said. The legislative history reveals no intent to attach a unique meaning to the commonly understood and well-established 'fair market value' term.'' Panel Report at 16.

A review of all floor statements offered at the time of passage of the 1994 amendments reveals considerable differences between the views of the two Chairmen and some of the members. These differences are accentuated by a later floor statement offered by Chairman Hughes when he introduced a bill that would make technical corrections to the 1994 Satellite Home Viewer Act. 140 Cong. Rec. E2290 (daily ed. November 29, 1994) (statement of Rep. Hughes).

The statement of Chairman DeConcini offers the greatest support to the argument that the rates established in this proceeding should approximate what cable pays under the cable compulsory license. 140 Cong. Rec. S14105 (daily ed. Oct. 4, 1994) (''I am confident that the arbitration panel will take steps to ensure that the royalty fee paid by satellite carriers are on par with those paid by cable operators''). Representative Synar's comments suggest his desire that a satellite rate adjustment produce rates comparable to the cable compulsory license, but he does not state that application of the fair market value standard should or must produce such comparability. The statements of Representative Brooks and Hughes provide that cable compulsory license rates are one of the factors to be considered by the Panel, but they do not indicate that they are the only or controlling factor.

The Register has consulted the caselaw in determining the weight to be accorded floor statements made by Congressmen during the passage of legislation. The caselaw provides that floor statements of legislators are to be given little weight *Garcia* v. *U.S.,* 469 U.S. 70, 78, (1984); *Zuber* v. *Allen,* 396 U.S. 168, 186 (1969) (''Floor debates reflect at best the understanding of individual Congressmen''). The reasoning behind this principle was aptly described by the Federal Circuit Court for the District of Columbia:

> [I]t is necessary for judges to exercise extreme caution before concluding that statement made in floor debate, or at a hearing, or printed in a committee document may be taken as statutory gospel. Otherwise, they run the risk of reading authentic insight into remarks intended to serve quite different purposes. Furthermore, to the degree that judges are perceived as grasping any fragment of legislative history for insights into congressional intent, to that degree will legislators be encouraged to salt the legislative record with unilateral interpretations of statutory provisions they were unable to persuade their colleagues to except * * *.

*Int. Broth. of Elec. Wkrs. Loc. U. 474* v. *NLRB,* 814 F.2d 697 (D.C. Cir. 1987) (Buckley, concurring); see also *Overseas Educ. Ass'n. Inc.* v. *FLRA,* 876 F.2d 960, 975 (D.C. Cir. 1989) (''While a sponsor's statements may reveal *his* understanding and intentions, they hardly provide definitive insights into *Congress'* understanding of the meaning of a particular provision'') (emphasis in original).

Of greater importance in discerning the intent of Congress, as opposed to the

statements of individual Members, is the fact that Congress changed the statute in 1994. When Congress decides to change a statute, the decision to do so signifies that it intended to change the meaning. *Brewster* v. *Gage*, 280 U.S. 327, 338 (1932); *United States v. NEC Corp.*, 931 F.2d 1493, 1502 (11th Cir. 1991); *In re Request for Assistance*, 848 F.2d 1151, 1154 (11th Cir. 1988), *cert. denied sub. nom., Azar* v. *Minister of Legal Affairs*, 488 U.S. 1005 (1989). That is what occurred here. If Congress had truly intended cable compulsory license rates to govern the adjustment of fees in this proceeding, then it would not have amended the statute in1994 to provide for a fair market value determination.[5]

In sum, while floor statements by some Members indicate an intent that fair market value be determined in various ways, by looking at the statute, committee reports, floor statements and colloquies the Register does not find any special meaning or limitation attached to the term ''fair market value'' and, therefore, must rely on the plain language of the statute and the plain meaning of the term. The Panel, in the view of the Register, therefore, did not act arbitrarily, or contrary to law in its interpretation of the meaning of ''fair market value.''

*B. The Cable Network Fee Benchmark*

1. Action of the Panel

In order to determine fair market value royalty rates as required by section 119(c)(3)(D), the Panel considered the voluminous testimony and exhibits presented by the parties. Witnesses for PBS, JSC, the Commercial Networks, SBCA, and ASkyB sponsored economic analyses and testified as to their calculation of fair market value. The copyright owners used empirical data of license fees paid to certain cable networks by multichannel video programming distributors (principally cable operators), while satellite carriers focused primarily on the license fees paid by cable operators under section 111.

The Panel specifically endorsed the approach taken by PBS, and its principal witness, Ms. Linda McLaughlin. Using data supplied by an industry survey group,[6] Ms. McLaughlin examined the license fees paid by multichannel video programming distributors (''MVPDs'') to license the viewing rights to 12 popular basic cable networks. These networks are A&E, CNN, Headline News, Discovery, ESPN, the Family Channel, Lifetime, MTV, Nickelodeon, TNN, TNT, and USA. Ms. McLaughlin testified that these basic cable networks represented the closest alternative programming to broadcast programming for satellite homes, and that studies indicated that consumers value networks and superstations as least as highly as popular basic cable networks. Direct Testimony of Linda McLaughlin at 2–5. She then calculated a ''benchmark'' rate for these networks to be used by the Panel as representative of the fair market value of broadcast signals retransmitted by satellite carriers:

> * * * I have calculated a basic cable network benchmark price and used it to estimate a minimum compulsory license fee for satellite-retransmitted broadcast stations. The average license fee of the 12 popular basic cable networks was 18 cents in 1992—when the maximum satellite compulsory rate was 17.5 cents—and has risen to 24 cents in 1995, an annual increase of ten percent per year. The license fees for these 12 basic cable networks are forecast to increase to an average of 26 cents in 1997, 27 cents in 1998 and 28 cents in 1999. This suggests that the compulsory rate for satellite retransmitted stations should increase at least correspondingly with the average prices for basic cable networks, to an average at least 27 cents for the 1997–99 period.

*Id.* at 7.

The Panel endorsed Ms. McLaughlin's approach because it determined that it represented the closest model, of those presented, to a free market negotiation for satellite carriage of broadcast signals, and because it was the most conservative approach offered by the copyright owners. Panel Report at 29–30. The Panel rejected the analysis of JSC (Testimony of Mr. Larry Gerbrandt) as too narrow,[7] and the analysis of the Commercial Networks (testimony of Mr. Bruce Owen) as too speculative.[8] The Panel also rejected the analyses of SBCA and ASkyB because it determined that their analyses did not comport with the plain statutory meaning of the term ''fair market value.'' *Id.* at 29–30.

2. Arguments of the Parties

SBCA contends that cable network license fees are not an appropriate benchmark because cable networks are fundamentally different from retransmission of broadcast signals. It asserts that ''[e]xtracting an accurate, or even representative license fee per subscriber is basically impossible because multiple programming services are included within contracts, there are ceilings on aggregate license fees for MVPDs in some cases, free subscriptions in others, marketing and launch support provided by the cable networks, purchases of advertising time by the cable networks from MVPDs, and equity investments by each in the other.'' SBCA Petition to Modify at 20–21.

In reply, Copyright Owners assert that the Panel acted properly by utilizing cable networks as the benchmark of fair market value, and accepting the analysis of Ms. McLaughlin. Copyright Owners not that they wished to examine the license fees paid by satellite carriers to cable networks in particular, as opposed to the fee paid by all MVPDs in general, but SBCA refused to disclose through discovery the amounts that satellite carriers paid. Copyright Owners Reply at 17. They further note that while SBCA's witness, Mr. Jerry L. Parker, stated that a meaningful license fee could not be determined from satellite/cable network contracts, SBCA never produced the documents to support that assertion. *Id.* at 18. Copyright Owners assert that Ms. McLaughlin testified that the license fees presented by her analysis demonstrated at least the minimum amount that satellite carriers would pay for cable networks, and that her analysis offered the best evidence that was properly accepted by the Panel. *Id.*

3. Recommendation of the Register

In the Register's view, the Panel's decision to use cable network license fees as a benchmark for establishing the fair market value of section 119 rates was the product of rational decisionmaking, and its decision to use the PBS/McLaughlin approach was not improper.

Having determined that ''fair market value'' meant the price that would be paid by a willing buyer and seller in a free marketplace, it was not illogical for the Panel to give careful consideration to evidence of markets that most closely resembled the licensing of signals under section 119. In fact, section 119(c)(3)(D)(i) requires that the Panel consider ''the cost for similar signals in similar private * * * marketplaces.'' 17 U.S.C. 119(c)(3)(D).

All three of the evidentiary presentations of the copyright owners—PBS, JSC, and Commercial Networks—

[5] There is no question that the principal factor for determining rates under the 1988 legislation was the rates paid by cable. 17 U.S.C. 119(c)(3)(B) (1988) (the Panel ''shall consider the approximate average cost to a cable system for the right to secondarily transmit to the public a primary transmission made by a broadcast station * * *.'').

[6] The data was supplied by Paul Kagan Associates, a leading information and data company in the video industry.

[7] Mr. Gerbrandt isolated the license fees paid for two basic cable networks: TNT and USA. Tr. 2025–2026.

[8] Mr. Owen used regression analysis in an attempt to demonstrate that MVPDs are willing to pay proportionally higher license fees for network signals which contain more expensive programming. Direct Testimony of Bruce Owen at 7–10.

focused upon the fees paid to cable networks by MVPDs. SBCA's evidence of fair market value, the cable license fees paid under section 111, was less relevant to the Panel's determination because the Panel had rejected the notion that cable fees equaled fair market value. Panel Report at 29–30. The Panel's adoption of cable network fees as the benchmark was not unqualified, however, because it stated that ''we agree with the satellite carriers that the economic model governing cable networks varies markedly from the economic model governing broadcasters.'' *Id.* at 29. Nevertheless, the Panel ''adopt[ed] the copyright owners' *general* approach using the *most similar* free market we can observe.'' *Id.* at 30. After reviewing the record, the Register has determined that the Panel's conclusion is not ''arbitrary'' within the meaning of 17 U.S.C. 802(f).

SBCA contends that cable network fees are not a useful benchmark because the economics of cable networks are fundamentally different from those of broadcast networks and superstations. SBCA Petition to Modify at 20 (citing testimony of Mr. Harry Shooshan, Mr. John Haring and Mr. Edwin Desser). The testimony of Mr. Shooshan and Mr. Haring, in particular, suggest that there are some marked differences between the licensing of cable networks and broadcast signals. The Panel, however, took account of that. Panel Report at 29. Nevertheless, there was ample testimony that the two markets were also quite similar. Tr. 1202–04 (Mr. Robert Crandall); Tr. 1609 (Ms. McLaughlin); Tr. 1284 (Mr. Owen). The Panel weighed the evidence and accepted the copyright owners' approach using cable network fees because it was ''the *most similar* free market we can observe.'' Panel Report at 30 (emphasis in original). Because this conclusion is grounded in the record, it is not arbitrary. *National Cable Television Ass'n, Inc.* v. *CRT,* 724 F.2d 176, 189 (D.C. Cir. 1983) (decisions grounded in the record within the zone of reasonableness).

Likewise, the Panel's decision to rely on the PBS/McLaughlin testimony to establish the cable network benchmark was adequately grounded in the record. Panel Report at 18–20. Again, the Panel stated that use of cable networks was by no means flawless and, to account for this, the Panel was adopting the ''conservative'' approach offered in Ms. McLaughlin's analysis. *Id.* at 31. The Register determines that the Panel's decision to accord the PBS/McLaughlin testimony controlling weight is consistent with its determination to utilize the plain meaning of ''fair market value'' as the proper standard for setting royalty fees. Further, it is well established that using evidence of analogous markets is the best evidence in determining market price. *See National Cable Television,* 724 F.2d at 187. For these reasons, the Register determines that the Panel did not act arbitrarily or contrary to the Copyright Act.

*C. Adjustments to the Cable Network Fee Benchmark*

1. Adjustment to the Benchmark for Delivery Costs

*a. Action of the Panel.* After establishing cable network license fees, as presented by Ms. McLaughlin, as the benchmark for determining the section 119 royalty rates, the Panel examined, *inter alia,* the special features and conditions of the retransmission marketplace to determine if an upward, or downward, adjustment in the benchmark was appropriate. One of the aspects of satellite retransmission of broadcast signals that differ significantly from the transmission of cable networks involved the costs of delivering the signals to the MVPDs. The Panel found this issue, along with that of advertising inserts (discussed *infra*), as being ''among the most challenging issues for the Panel to resolve.'' Panel Report at 43.

The Panel found that the license fees charged for cable networks included the cost of delivering the cable network to the MPVD—i.e., making the signal readily available for reception by the MVPD for subsequent distribution to subscribers. *Id.* at 45. With satellite retransmission of broadcast signals, however, the satellite carriers absorb the costs of getting the broadcast signal from its geographic point of origin, and then delivering it to its subscribers. *Id.* The Panel considered whether the cost of delivering the signals should, therefore, be deducted from the benchmark.

The Panel declined to make such a deduction. The Panel found that there was no evidence presented to suggest that if satellite carriers and copyright owners negotiated in a free marketplace for the retransmission of broadcast signals, the copyright owners would offer satellite carriers a discount on license fees to accommodate delivery costs. The Panel discussed the testimony of Mr. Jerry L. Parker, an SBCA witness who offered testimony as to the history, nature and operation of the satellite industry:

> Mr. Parker was invited to demonstrate whether carrier costs impacted the rates negotiated between satellite carriers and cable networks. He could not. Indeed, Mr. Parker conceded, for example, that despite additional costs incurred by DBS [9] carriers (beyond those of HSD [10] carriers), DBS operators were unable to negotiate lower rates on that basis. Moreover, he declined to urge the Panel to set a discounted rate for DBS carriers to account for their higher costs than HSD carriers. We must similarly decline to discount the cable network benchmark to account for higher delivery costs of broadcast signals.

Panel Report at 45–46 (citations omitted).

*b. Arguments of the Parties.* SBCA vigorously contests the Panel's resistance to deducting delivery costs from the 27 cent benchmark figure, stating that ''it must be recognized that all cable networks that are charging and receiving 27 cents have made the necessary investment and expense in distributing the signal * * *. None of the [c]opyright [o]wners or broadcasters in this proceeding incurred this necessary expense for satellite distribution of superstations or network stations.'' SBCA Petition to Modify at 22. SBCA cites the testimony of Ms. McLaughlin, who acknowledged that broadcast stations are not responsible, and do not incur the cost of, delivering their signal to satellite carriers for subsequent retransmission. *Id.* at 22–23. SBCA submits that ''[t]he error in Ms. McLaughlin's analysis, implicitly accepted by the Panel, is that these expenses were basically the cost of the [s]atellite [c]arriers in distributing their own product.'' *Id.* at 23. SBCA asserts that the Panel understood that satellite carriers bore the cost of delivery, but then mistakenly categorized it as a ''discount'' to compensate carriers for their costs, when in fact it is a cost that must be borne by the copyright owners. *Id.* at 25–26.

SBCA submits that it demonstrated that the average delivery cost per signal, per subscriber, per month is 10 cents, and 6.5 cents for volume discounts. SBCA, therefore, contends that the 27 cent benchmark rate must be adjusted downward to between 17 and 21.5 cents. *Id.* at 23, f.n. 53.

In reply, Copyright Owners assert that SBCA mischaracterizes the transmission cost issue by suggesting that the major focus should be the structural nature of such costs, rather than whether they would result in any marketplace price adjustments. Copyright Owners Reply at 22. Copyright Owners cite Mr. Larry Gerbrandt's testimony that transmission

[9] ''DBS'' stands for Direct Broadcast Service, and is associated with high powered, high frequency direct broadcast satellite services. An example of a DBS operator is DirecTV.

[10] ''HSD'' stands for ''Home Satellite Dish,'' and typically refers to satellite providers who operate at lower frequencies than DBS providers.

costs do not yield different cable network license fees in the marketplace, and note that Mr. Jerry Parker was unable to demonstrate otherwise. *Id*. at 22–23.

*c. Recommendation of the Register.* The Panel discussed the issue of transmission costs quite extensively, finding that the record was devoid of credible evidence demonstrating that transmission costs of satellite carriers affected the rates negotiated between satellite carriers and cable networks. Panel Report at 45–46. The Panel expressly found that SBCA's witness. Mr. Parker, could not offer evidence of such an impact, and conceded that despite additional costs incurred by DBS carriers, DBS operators were unable to negotiate lower rates on that basis. Tr. 2528. The Panel grounded its determination in the record evidence, which is the hallmark of rational decision making. *National Cable Television Ass'n.* v. *CRT*, 724 F.2d 176 (D.C. Cir. 1983).

SBCA's discussion of transmission costs fails to focus on what impact, if any, they would have on negotiated license fees, and instead relates to which party should bear the cost. Costs can be shifted between parties in a business relationship, and SBCA asserts that their costs, when comparing delivery of broadcast signals with delivery of cable networks, must be shifted to copyright owners to prevent a windfall. However, costs can also be absorbed by a party as part and parcel of doing business, and must be when one party cannot shift the costs (or a portion thereof) to the other. Where there is no credible evidence demonstrating a party's ability to shift a cost, no change in the negotiated price should occur. The Panel found that to be the situation with transmission costs, and the Register has no grounds on which to reject that finding.

2. Adjustment to the Benchmark for Advertising Inserts

*a. Action of the Panel.* In addition to delivery costs, the Panel considered the issue of advertising inserts very significant. Cable networks typically grant MVPD's a certain number of time slots during the programming provided—known as advertising inserts—for the MVPDs to sell to advertisers. The monies raised from these inserts are retained by the MVPD, and can defray the cost of the license fee for the cable network approximately 8 cents per subscriber per month. Panel Report at 43–44. The Panel found, however, that because section 119(a)(4) requires satellite carriers to retransmit the signals of broadcast stations intact, they do not receive any advertising inserts for the retransmission of broadcast signals. *Id*. at 44. The Panel considered whether this should result in a downward adjustment of the benchmark rate.

The Panel declined to make an adjustment:

> [T]he satellite carriers naturally argue that because the benchmark is based upon the rate paid by multichannel distributors to cable networks, we must deduct $0.08 to obtain the 'real cost' of cable networks. The copyright owners counter that most satellite carriers don't insert advertising into cable network signals anyway. Indeed, HSD carriers don't possess the technology to insert advertising. Moreover, multichannel distributors *appear* to pay the same cable network license fee regardless of whether they insert advertising.
>
> If this last assertion is accurate, one would expect that in a hypothetical free market negotiation, broadcasters would similarly decline to reduce their license fees to satellite carriers for their lack of advertising availabilities and no benchmark adjustment would be appropriate. Both Ms. McLaughlin and Mr. Gerbrandt opined that, based upon their knowledge and experience, neither the availability of advertising inserts, nor the carriers [sic] ability to insert, affects the prices that cable networks charge. They did not support this opinion with any documentary evidence or empirical data. However, the satellite carriers allowed this testimony to stand essentially unrefuted. Indeed, Dr. Haring was explicitly invited to render an opposing opinion but forthrightly declined. In the final analysis, we accept the copyright owners' expert testimony and decline to deduct $0.08 from the benchmark as advocated by the satellite carriers.

Panel Report at 44–45 (citations omitted).

*b. Arguments of the Parties.* SBCA alleges that the Panel ''completely misconceived the adjustment necessary to reflect the value for insertable advertising.'' SBCA Petition to Modify at 26. They note that the arbitration panel in the 1992 rate adjustment made a downward adjustment for advertising inserts. 57 FR 19058 (May 1, 1992). SBCA asserts that the ''value of insertable advertising is significant,'' and that its value is ''no less than 7.5 cents'' per subscriber per month. *Id*. at 27.

As a ''variation'' on the advertising insert issue, SBCA offers that the increased national exposure of broadcast stations offered by satellite retransmissions increases the amount of revenue that copyright owners receive for the advertising slots that they retain. *Id*. at 28. SBCA submits that the Panel should have further adjusted downward for this value, and argues that it could not quantify the value because the necessary information was in the possession of the copyright owners who were not required to disclose it through the CARP discovery rules.[11]

In reply, Copyright Owners assert that the Panel fully considered the arguments of SBCA, and correctly rejected any downward adjustments for advertising inserts. Copyright Owners Reply at 23–24.

*c. Recommendation of the Register.* The Panel fully discussed what effect, if any, advertising inserts might have on the negotiated fee for retransmission of broadcast signals. Panel Report at 43–45. The Panel cited the testimony of Ms. McLaughlin and Mr. Gerbrandt that ''based upon their knowledge and experience, neither the availability of advertising inserts, nor the carriers ability [sic] to insert, affects the prices that cable networks charge * * *. The satellite carriers allowed this testimony to stand essentially unrefuted. Indeed, Dr. Haring was explicitly invited to render an opposing opinion but forthrightly declined.'' *Id*. at 44. SBCA did not offer any testimony which incontrovertibly rebuts the testimony of Ms. McLaughlin and Mr. Gerbrandt. Consequently, the Panel's determination that no adjustment should be made is not arbitrary because it is grounded in the record.

*D. Equality Between Superstation and Network Signal Rates*

1. Action of the Panel

As discussed above, Congress established different royalty rates for superstation and network signals when it created the section 119 license. The initial rate for superstations was 12 cents per subscriber per month, and 3 cents per subscriber per month for network signals. This 4 to 1 ratio reflected the payment of royalties under the section 111 license. Under section 111, only copyright owners of nonnetwork programming are allowed to share in the royalty funds. Cable operators pay full value for retransmitting independent broadcast stations (of which superstations are a subset), and only one-quarter value for retransmission of network signals. 17 U.S.C. 11(f). The one-quarter value reflects Congress' determination in 1976 that approximately 25 percent of the programming on network signals is compensable nonnetwork programming, while the remainder is not. Congress

[11] SBCA alleges throughout its Petition to Modify that the CARP discovery rules, and particularly the Panel's application of the rule, precluded it from obtaining vital information from copyright owners to support its case, which resulted in negative inferences by the Panel as to the sufficiency of its presentation. This argument is addressed, *infra* in subsection G.

carried over this 4 to 1 ratio in the 1988 Satellite Home Viewer Act when it set the 12 cent and 3 cent rates in the statute.

The 1992 arbitration panel that adjusted the section 119 rates took into account the 4 to 1 ratio, but found that the amount of network programming on network stations had declined to approximately 50 percent, down from the 75 percent contemplated by section 111. That panel, however, set the network station rate at 6 cents, which represented roughly a 3 to 1 ratio to the superstation rate it set, because it was concerned with disruption in the satellite industry of carriage of network signals if it established a network signal rate at half (a 2 to 1 ratio) that of the superstation rate. 57 FR 19052, 19060 (May 1, 1992). The Copyright Royalty Tribunal, in reviewing the panel's decision on this matter, stated that:

> The Tribunal believes that the Panel was not bound by either a 4:1 ratio or a 1:1 ratio. When the Tribunal issued its declaratory ruling concerning network copyright owners, we did not intend to prejudge any future ratesetting. We noted that in cable and satellite, the pay-in may not necessarily correlate to the pay-out. Therefore, a 1:1 ratio is not required. However, we do believe the Panel had the authority to take our declaratory ruling into account, so that it was entitled to adjust the 4:1 ratio downward to reflect that network copyright owners are entitled to receive satellite royalties.

*Id.* at 19052.

The Panel in this proceeding rejected the notion that it was required to set different royalty rates for superstations and network signals, respectively, because it was seeking the fair market value of these signals. The Panel stated:

> We find no credible evidence that retransmitted network stations are worth less than retransmitted superstations. Indeed, even assuming *arguendo,* we were to conclude that network programming is worth less, or even wholly uncompensable, we find no record support for any particular ratio—no evidence was adduced as to the *present day* average proportion of network to non-network programming. And imposition of the original 4 to 1 ratio by rote, merely to replicate section 111 rates, would not be consistent with a fair market value analysis.

Panel Report at 40.

2. Arguments of the Parties

SBCA challenges the Panel's refusal to apply the 4 to 1 ratio, asserting that such ratio is binding precedent upon the Panel. SBCA Petition to Modify at 38. SBCA contends that Congress determined, under section 111, that network programming is not compensable, and carried this rationale into the rate structure of section 119. The fact that networks are allowed to share in the section 119 royalties, but not the section 111 royalties, ''does not mean that the network signals are to be paid for any differently under the satellite license than under the cable license * * *'' *Id.* at 39. Furthermore, SBCA submits that satellite carriers give added value to network signals by carrying them to unserved households who would not otherwise receive such signals. *Id.* at 41. SBCA contends that, if anything, there should be no fee for network signals. *Id.* at 40.

Finally, SBCA argues that the Panel erred by creating a 27 cent royalty rate applicable to PBS (defined under the statute as a network) because ''PBS signals are free on the satellite by law.'' *Id.* at 41. These signals, SBCA contends, cannot possibly have a market value, and there should be no royalty fee for PBS signals. *Id.*

Copyright Owners contend that the Panel correctly rejected the 4 to 1 ratio because the new law requires a determination of fair market value. Copyright Owners Reply at 32. Copyright Owners note that the binding precedent referred to by SBCA was an interpretation of the 1988 Satellite Home Viewer Act, not the 1994 Act, and that nothing in the 1994 Act requires assignment of different rates for superstation and network signals. *Id.* at 33–34.

With regard to SBCA's contention that retransmission of PBS signals should not be compensated at the 27 cent level, Copyright Owners argue that such a contention ''flies in the face of the fair market value evidence,'' and that the PBS signal available for free on the satellite is not the signal of the member stations that are at issue in this proceeding. *Id.* at 35.

3. Recommendation of the Register

The Panel did not err by rejecting the 4 to 1 ratio and adopting a network signal rate that was equal to the value of the superstation rate. The Panel correctly observed that while the 1992 arbitration panel generally followed the ratio set by Congress in the 1988 Act, the 1994 amendments changed any reliance upon a pre-set ratio by directing the Panel to determine only the fair market value for network and superstation signals. Panel Report at 40. There is not evidence in the 1994 Act, or its legislative history, that Congress intended the Panel to set a rate for network signals that is one-fourth of that for superstations (or any other ratio, for that matter) if that rate did not represent the fair market value of network signals.

SBCA asserts that the 1994 amendments contemplate a CARP establishing two rates—one for network signals, and another for superstations—thereby inferring that Congress contemplated rate differentiation (i.e. that one rate would be less than the other). Such an inference is belied by language in the House Report, however, which states that the rates set by the CARP in this proceeding ''should reflect the fair market value of satellite carriers' secondary transmissions of superstations and network stations.'' H.R. Rep. No. 703, 102d Cong., 2d Sess. 7 (1994). The statute does not require or suggest that the rate for network signals, or superstations, be set at anything less than fair market value.

There is no binding precedent that required the Panel to apply a ratio in value between network signals and superstations, and set network signal rates lower than superstation rates. The 1992 arbitration panel applied a different criterion (rates paid by cable under section 111) to determine section 119 rates, and its decision therefore does not serve as precedent for this proceeding. Furthermore, even if the 1992 arbitration were binding precedent, the final order of the Copyright Royalty Tribunal (which constituted the final agency action in that proceeding) clearly stated that no differentiation between network and superstation rates was required. 57 FR 19052 (May 1, 1992) (''The Tribunal believes the Panel was not bound by either a 4:1 ratio or a 1:1 ratio.''). The Panel, therefore, did not act arbitrarily by rejecting application of the 4 to 1 ratio.

The Register has also examined the record to determine whether, under a fair market value analysis and regardless of application of a pre-set ratio, the evidence required a differentiation in network and superstation rates. The Panel determined that there was ''no credible evidence that retransmitted network stations are worth less than retransmitted superstations.'' Panel Report at 40. It was wholly within the Panel's discretion to arrive at such a determination. SBCA presented evidence demonstrating that network viewer ratings have declined, SBCA Proposed Findings of Fact and Conclusion of Law at 39, but it did not offer evidence as to what impact such a decline had relative to superstations, nor did it quantify the difference in value between network signals and superstations under a fair market value analysis, except to insist that all signals should be free. *See* SBCA Reply Findings of Fact and Conclusions of Law at 7. The Panel, consequently, did not act arbitrarily by adopting the same royalty rate for both network signals and superstations.

Finally, SBCA argues that because the Panel failed to take account of the fact that PBS signals are free on the satellite by law, it was error to accord them the same royalty rate as other network signals.[12] Section 605(c) of the Communications Act, 47 U.S.C., prohibits encryption of programs included in the National Program Service of the Public Broadcasting Service, essentially making the National Program Service free to all satellite home dish owners. Member stations of PBS, however, are not subject to 47 U.S.C. 605(c), and satellite carriers may charge their subscribers for retransmission of these stations. Furthermore, the National Program Service is not a network signal as defined under section 119(d)(2). Member stations of PBS are network signals under section 119(d)(2). Presumably, there are PBS programs available on the National Program Service that are the same programs available from PBS stations, although no such evidence was adduced in this proceeding. There are also likely to be different programs, particularly those produced by member stations. SBCA did not quantify by how much, under a fair market value analysis, the same programs on the National Program Service and PBS stations should reduce the royalty fee for PBS stations, beyond a blanket assertion that all PBS stations should be free. SBCA Reply Findings of Fact and Conclusions of Law at 68–69. The Panel concluded that there was ''no credible evidence'' warranting a conclusion that network signals were worth less, which would include PBS stations. The Register cannot find credible evidence to the contrary, and therefore the Panel's determination must be affirmed.

*E. Local Retransmission of Network Signals*

1. Action of the Panel

In setting the satellite carrier compulsory license royalty rates for networks and superstations, the Panel was asked to distinguish between satellite retransmission of ''distant'' broadcast signals, and satellite retransmissions of ''local'' broadcast signals. The Panel did make this distinction, setting a royalty rate of 27 cents for distant retransmission of superstations, and zero cents for local retransmission of superstations. Panel Report at 54.

While the Panel adopted a 27 cent rate for retransmission of distant network signals, *id*., it declined to adopt a rate for local retransmission of network signals because it determined that it lacked subject matter jurisdiction to do so. *Id*. at 48. The Panel considered section 119(a)(2)(B), which provides that the satellite compulsory license is ''limited to secondary transmissions to persons who reside in unserved households,'' and examined the section 119(d)(10) definition of an unserved household. The Panel concluded that:

> [N]etwork signals generally may not retransmitted to the local coverage area of local network signals. The separate rate request of ASkyB is explicitly intended to apply to retransmission of network signals to *served* households. Section 119 does not provide a compulsory license for these retransmissions. Hence, we lack subject matter jurisdiction to set a rate for local retransmissions of local *network* signals.

Panel Report at 48 (emphasis in original).

The Panel did acknowledge in a footnote that there may be ''rare instances'' where a household located within the local market of a network signal was, indeed, an unserved household within the meaning of section 119(d)(10). *Id*. at 48, f.n. 62. The Panel stated that ''[t]hese households qualify as unserved but, under section 119, ASkyB would pay the conventional 'rate for non-local signals.' '' *Id*.

2. Arguments of the Parties

EchoStar contends that the Panel committed reversible error in determining that it has no jurisdiction to set a royalty rate for local retransmission of network signals, and that the rate should be zero. EchoStar Petition to Modify at 1. According to EchoStar, the language of section 119 regarding the permissibility of local retransmission of network signals is nuclear, and the Panel should therefore have consulted the legislative history, rather than decide the matter on the basis of the statutory language. *Id*. at 7–8. EchoStar submits that the Congressional intent behind the unserved household restriction of section 119(a)(2)(B) was to protect the network-affiliate relationship from importation of distant signals of the same network, citing the recent Copyright Office Report on revision of the cable and satellite carrier compulsory licenses. *Id*. at 4. Because local retransmissions do not harm the network-affiliate relationship, EchoStar asserts that ''[i]n light of the intent behind the compulsory license, therefore, the 'unserved household' limitation should be read as not precluding such local-into-local retransmissions—a form of retransmission which required technologies not in existence at the time of the legislation.'' *Id*. at 5.

In addition, EchoStar submits that the Panel should have interpreted section 119 flexibly enough to allow local retransmission of network signals, citing *Sony Corp. of America* v. *Universal City Studios, Inc.*, 464 U.S. 417 (1984) and *Twentieth Century Music Corp.* v. *Aiken*, 422 U.S. 151 (1975). *Id*. at 10. Finally, EchoStar argues that, since the section 119 license was modeled after the section 111 license, and local retransmission of network signals is permitted under section 111, the two statutes should be interpreted similarly. *Id*. at 11 (citing *Northcross* v. *Board of Education*, 412 U.S. 427 (1973).

Commercial Networks seek a clarification of the Panel's ruling on local retransmission of network signals, albeit from a completely different perspective. Commercial Networks request the Librarian to make clear that where local retransmission of a network signal does not violate the unserved household restriction (a circumstance acknowledged by the Panel likely to be rare), the rate for such retransmission is 27 cents per subscriber per month. Commercial Networks Petition to Modify at 1.

In reply, EchoStar opposes Commercial Networks position, and argues that the same rationale that the Panel used in adopting the zero rate for superstations applies with equal force to network stations that are locally retransmitted to unserved households. EchoStar Reply at 2.

Certain Copyright Owners object to EchoStar's position, and contend that EchoStar does not have standing under the rules to file a petition to modify the Librarian's decision when it was not an active party in this proceeding. Certain Copyright Owners Reply at 1. Certain Copyright Owners contend that the Panel correctly interpreted section 119 as preventing retransmission of local network signals to served households, and that the legislative history does not warrant a different conclusion. *Id*. at 3–6.

3. Recommendation of the Register

Two separate issues are presented by the local retransmission of network signals. First, there is the retransmission of a network station within that station's local market. The Panel categorized this as local retransmission to served households, and concluded that section 119 did not permit such retransmissions. Second, there is retransmission of a network station within that station's local market to subscribers who satisfy the definition of an ''unserved household'' in section

[12] PBS signals are defined as network stations under section 119(d)(2).

119(d)(10). The Panel acknowledged that such retransmissions were permissible under section 119, though likely to occur in ''rare instances,'' but was unclear as to what the proper royalty rate should be.

Local retransmission of network signals to served households presents a challenging issue. The Copyright Office declined to issue a declaratory ruling that such retransmissions are permissible, though it did not preclude addressing such a matter through a rulemaking procedure. Letter of the Acting General Counsel to William Reyner, August 15, 1996. Moreover, the Office has, in its recent report to the Senate on revision of the satellite and cable compulsory licenses, expressly endorsed the permissibility of such retransmissions, and requested Congress to ''clarify'' the statute on the matter. ''A Review of the Copyright Licensing Regimes Covering Retransmission of Broadcast Signals,'' Report of the Register of Copyrights at xx (1997) (hereinafter ''Register's Report''). As the agency responsible for administering the Copyright Act, the Office believes that it retains the authority to conduct a rulemaking proceeding to determine the permissibility of local retransmission of network signals to served households, regardless of the Panel's determination in this proceeding.

Nevertheless, the Register must determine whether the Panel's decision that such retransmissions are not permitted under section 119 is contrary to the provisions of the Copying Act.[13] The Register reviewed the language of section 119, and its legislative history, both in the context of this proceeding, and in her report to the Senate. Such review confirmed the Register's belief that Congress simply did not consider the issue of local retransmission of network signals to served households at the time of passage of section 119, principally because the technology to make such local retransmission did not commercially exist. It is evident from the history surrounding adoption of the unserved household restriction in 1998 that adoption of the restriction was motivated by concerns expressed by network affiliate stations that importation of distant network stations affiliated with the same network would erode their over-the-air viewership. Register's Report at 103–104. This suggests that if Congress had considered the issue, it might have condoned local retransmissions to served households. On the other hand, the section 119(d)(10)(A) portion of the definition of an ''unserved household'' does not specify receipt of what network signal over-the-air triggers the prohibition in making retransmissions of network signals. The language of section 119(d)(10)(A) could easily be read to prohibit retransmission by satellite whenever the subscriber receives an over-the-air signal of Grade B intensity from any network affiliate, including the local network affiliate that the satellite carrier intends to retransmit to the subscriber. This is the position that the Panel took.

In sum, the Register determines that the law is silent on this issue. Consequently, the Register cannot unequivocally say that the Panel's decision is arbitrary or contrary to law.

The second issue is the local retransmission of network signals to unserved households. The Panel appears to have presumed that such retransmissions are permissible. Panel Report at 48. The Register determines that they are permissible, as provided by the express terms of section 119. The Panel failed to articulate what royalty rate would be applicable to such local retransmissions. It mentioned, in a footnote, that the number of unserved households within a network station's local market were likely to be few, and cited the testimony of ASkyB's witness, Preston Padden, that ASkyB would, in those instances, ''pay the conventional 'rate for non-local signals.' '' *Id.* at 48, f.n. 62 (quoting written direct testimony of Mr. Padden). The Panel did not expressly state what the rate should be for all carriers making local retransmissions of network signals to unserved households.

Commerical Networks urge that the rate for such retransmissions should be 27 cents. EchoStar[14] argues that the rate should be zero, consistent with the Panel's adopted rate for local retransmissions of superstations. To the extent that the Panel sought to impose the 27 cent rate on local retransmissions of network signals to unserved households, the Register determines that such action is arbitrary. The Register cannot find testimony in the record that supports the conclusion that local retransimssion of network signals to unserved households has a fair market value rate of 27 cents, particularly where the Panel determined that the fair market value of local retransmissions of superstations was zero. Panel Report at 52. Likewise, the record does not support a conclusion that there is any differentiation between the fair market value of local retransimssions of network signals vis-a-vis superstations. Commercial Networks do not cite any testimony to the contrary in their petition to modify.

To the extent that the Panel failed to adopt a rate for local retransmissions of network signals to unserved households, the Register determines that such action is inconsistent with its task in this proceeding, and recommends that the Librarian substitute his own determination. 17 U.S.C. 802(g). The dearth of testimony on this issue and, for that matter, the Panel's cursory discussion of it, is not surprising because local retransmission of network signals to unserved households, and served households as well, is undoubtedly an unattractive business proposition to satellite carriers. Nevertheless, the issue was before the CARP, and requires a resolution.

The Register recommends that the Librarian adopt a zero rate for local retransmissions of network signals to unserved households because the Register is persuaded that the Panel's conclusions with respect to local retransmissions of superstations are equally applicable to local retransmissions of network signals to unserved households. Panel Report at 52-53. As noted above, there is no conclusive evidence to suggest that locally retransmitted network signals are of greater fair market value than locally retransmitted superstations. Accordingly, the Register recommends adoption of a zero rate for local retransmission of network signals to unserved households.

*F. Effective Date of the New Rates*

1. Action of the Panel

In announcing the royalty rate of 27 cents for distant retransmission of network and superstation signals, and zero cents for local retransmission of superstations, the Panel stated that the time period for payment of the rates would be from July 1, 1997, through December 31, 1999. Panel Report at 54.

2. Arguments of the Parties

SBCA contends that the Panel acted contrary to law by setting an effective

[13] Because the Panel's decision on this point is a conclusion of law, the arbitrary standard is not applicable.

[14] The Register agrees with Copyright Owners that EchoStar lacks standing to file a petition to modify the Panel's determination, and recommends dismissal of the petition. Section 251.55(a) of the rules, 37 CFR provides that only parties to the proceeding may file petitions to modify, and makes no provision for nonparties. EchoStar, though a member of, and represented by SBCA, was not a party to this proceeding because it did not file a Notice of Intent to Participate as required by the rules. *See* 37 CFR 251.45(a).

Dismissal of EchoStar's petition, however, does not preclude consideration of the issues surrounding local retransmissions of network signals, and the Register has considered these as required by section 802(g).

date of July 1, 1997, for the new rates. SBCA states that the Panel did not have any authority to set an effective date because section 119(c)(3)(C) states that the rates become effective as set forth in the Librarian's order. SBCA Petition to Modify at 46. Further, SBCA argues that the effective date of the new rates must be prospective only. *Id.* at 47. It notes that section 119 contemplates prospective application by discussing the rates ''to be paid.'' *Id.* at 48–49 (citing section 119(c)(3)(A) and the 1988 House Report to the Satellite Home Viewer Act). SBCA argues that the caselaw prevents retroactive application of agency rulemaking unless the enabling statute expressly states otherwise, and submits that the Librarian's order in this proceeding effectively constitutes a rulemaking because the Copyright Office's rules are being amended to reflect the new rates. *Id.* at 50–51.

Additionally, SBCA argues that applying the July 1, 1997, effective date would cause substantial harm to the satellite industry. *Id.* at 55. SBCA submits affidavits of representatives of the satellite industry discussing their inability to adequately inform their subscribers on a timely basis of the rate increase, and the difficulty of adjusting distribution contracts to accommodate fee increases. *Id.* at attachment A.

Finally, SBCA takes the Librarian to task for not complying precisely with the procedural schedule established in the statute for this proceeding. Specifically, SBCA contests the Library's decision to temporarily suspend the schedule to address issues raised by ASkyB, so that the CARP was initiated on March 3, 1997, as opposed to January 1, 1997, as contemplated in section 119(c)(3)(A). SBCA argues that because the Library violated the time requirement of section 119(c)(3)(A), and such delay caused substantial harm to satellite carriers, ''the Panel's report should be invalidated on due process grounds, particularly with respect to the prejudicial effective date directly resulting from the Librarian's failure to comply with a critically important statutory requirement.'' *Id.* at 55 (citing *Baumgardner* v. *Secretary, Dept. of Housing and Urban Development,* 960 F.2d 572 (6th Cir. 1992).

Copyright Owners assert that they have interpreted section 119 from the beginning of this proceeding as requiring an effective date of July 1, 1997, for the new rates, and that SBCA never challenged that position until now, thereby estopping SBCA from raising the issue. Copyright Owners Reply at 42–43. Copyright Owners also argue that the Librarian's good cause delay in commencing this proceeding does not invalidate it, and that the cases cited by SBCA are inapposite. *Id.* at 44–45. Copyright Owners also attach an accompanying motion to strike the affidavits offered by SBCA to corroborate its argument that the July 1 effective date will cause undue hardship on satellite carriers. SBCA opposes this motion.

3. Recommendation of the Register

Section 119(c)(3)(C) provides that:

> The obligation to pay the royalty fee established under a determination which—
>
> (i) is made by a copyright arbitration royalty panel in an arbitration proceeding under this paragraph and is adopted by the Librarian of Congress under section 802(f), or
>
> (ii) is established by the Librarian of Congress under section 802(f) shall become effective as provided in section 802(g) or July 1, 1997, whichever is later. 17 U.S.C. 119(c)(3)(C). Clause (i) of section 119(c)(3)(C) described the situation where the Librarian adopts the decision of the CARP, while clause (ii) describes the situation where the Librarian has rejected the CARP's decision and substituted his own determination.[15] The effective date of the established rates is either July 1, 1997, or the date set pursuant to section 802(g), whichever date is later.

Section 802(g) governs judicial review of the Librarian's decision in this proceeding. The section gives ''any aggrieved party who would be bound by the [Librarian's] determination,'' 30 days in which to notice an appeal with the United States Court of Appeals for the District of Columbia Circuit. The section then provides that ''[i]f no appeal is brought within such 30-day period, the decision of the Librarian is final, and the royalty fee * * * *shall take effect as set forth in the decision.*'' (emphasis added). Section 802(g) then provides that if an appeal is taken, ''[t]he pendency of an appeal under this paragraph shall not relieve persons obligated to make royalty payments under section ( ) * * * 119 * * *'' Nothing else is said in section 802(g) with regard to the possible effective date of royalty rates.

SBCA and Copyright Owners strongly disagree over the effective dates of the royalty rates established in this proceeding. SBCA believes that the effective date can be no sooner than 30 days after the Librarian's decision (i.e. November 26, 1997) at which time it will be known whether or not the Librarian's decision is final, while the Copyright Owners maintain that July 1, 1997, is the proper effective date. The Register has examined the governing language of sections 119(c)(3)(C) and 802(f), and notes an incongruity with respect to the July 1, 1997, date.

Section 119(c)(3)(A) provides that this proceeding was supposed to have started on January 1, 1997. Given the 180-day arbitration period, as provided by section 802(e), the latest the Panel could have delivered its report would have been June 29, 1997. The Librarian would then have the 60-day review period in which to either accept or reject the Panel's decision, which would place the date of final agency action at no later than August 28, 1997. This is almost two months after July 1, 1997. While Congress could have contemplated the Librarian completing his review in less than 60 days, it is hard to imagine that Congress could have expected him to complete it in just one day: the time period from delivery of the Panel's report on June 29 to the issuance of the Librarian's decision on July 1, 1997. The more likely explanation is that Congress envisioned the CARP delivering its report well before—at least two months—the 180-day deadline. Only in this manner could the Librarian have issued a decision that was before July 1, 1997, thereby justifying inclusion of the language ''July 1, 1997,'' and ''whichever date is later'' in section 119(c)(3)(C).

Contrary to the assertions of the Copyright Owners, July 1, 1997, is not the statutorily prescribed effective date for the new royalty rates announced in today's decision. July 1, 1997, is only a contingency date in the event that this proceeding had ended before July 1, 1997, which it clearly did not. Rather, the Register must look to section 802(g), which provides that the effective date of the new rates is ''as set forth in the decision.'' 17 U.S.C. 802(g). The Register interprets ''decision'' to mean the decision of the Librarian, and not the decision of the CARP, since section 802(g) only refers to the decision of the Librarian. Consequently, the Register concludes that only the Librarian of Congress has the authority to set the effective dates of the royalty rates in this proceeding, and it was contrary to law for the Panel to announce an effective date. *See* Panel Report at 54. The Register recommends that the Librarian reject the Panel's determination of an effective date.

The remaining issue is, if the Panel had no authority to set the effective date, what is the correct effective date for the Librarian to establish? Neither the statute, nor the legislative history, offers any guidance on this point.

[15] Interestingly, the statute does not address the situation, as in this proceeding, where the Panel's decision is accepted in part and rejected in part. Subclause (ii) most likely applies to this proceeding because the Librarian has established one of the royalty rates (the rate for local retransmission of network signals to unserved households).

Copyright Owners urge the July 1, 1997 date, and submit that SBCA is estopped from arguing for a later date since SBCA did not object to Copyright Owners' request to the Panel for a July 1, 1997, effective date. Copyright Owners Reply at 43–44. The Register recommends rejecting Copyright Owners' estoppel argument because the Panel did not have authority to set the effective date, and the matter is now being properly raised before the Librarian for the first time.

Copyright Owners also contend that July 1, 1997, must be the date because the evidence it presented to the Panel, particularly the PBS/McLaughlin testimony, was premised on a July 1, 1997, date. *Id.* at 42. According to Copyright Owners, if the Librarian adopts an effective date of January 1, 1998, he would have to increase the 27 cent fee to reflect the Panel's understanding of a thirty-month effective period for the new rates. *Id.* at 42–43.

The Register recommends rejection of Copyright Owner's contention for two reasons. First, the Panel accepts Ms. McLaughlin's testimony as a general matter to establish a workable benchmark. Panel Report at 31. The Panel did not accept her testimony, and its accompanying premises and assumptions, as *the* precise analysis of what the royalty rates should be. *Id.* Furthermore, although the Panel stated that ''Ms. McLaughlin's analysis yielded a rate of $0.27 per subscriber per month averaged over the three year statutory period,'' Panel Report at 30, a July 1 effective date accounts for only half of the year, and Ms. McLaughlin did not so limit her testimony. PBS Proposed Findings of Fact and Conclusions of Law at 18–19.[16]

In the Register's view, an effective date later than July 1, 1997, does not significantly undermine the Panel's use of the 27 cent benchmark generally, or its later decision to adopt that figure specifically, nor does a later effective date require an upward adjustment.

The second, and most significant, reason for not setting the effective date at July 1, 1997, involves the issue of retroactive rulemaking. Although the Librarian's decision today involves review of the Panel's determination, it is also a final rule with respect to setting the rates. The Copyright Office has previously determined that it lacks the authority to engage in retroactive rulemaking. 54 FR 14217 (1989). The United States Court of Appeals for the District of Columbia Circuit, the only court with jurisdiction to consider an appeal of today's decision, has expressly held that the Copyright Act does not confer retroactive rulemaking authority. *Motion Picture Ass'n of America, Inc.* v. *Oman*, 696 F.2d 1154, 1156 (D.C. Cir. 1992). The Register does not believe that the Librarian has the authority to set an effective date for the new royalty rates which is prior to the issuance of today's decision.

Given this limitation, the issue still remains regarding the proper effective date. Copyright owners obviously desire an effective date as soon as possible, so that they may reap the benefits of the higher rates. There are, however, significant administrative considerations surrounding implementation of the new rates. Satellite royalty rates are calculated on a monthly basis, so that an effective date other than the first day of a month will require application of two sets of royalty rates (the old rates and the new rates) to one monthly calculation. The Register finds this not only burdensome to satellite carriers calculating the rates, but to the Copyright Office as well in administering the section 119 license and examining the statement of account. The Register, therefore, counsels against adopting an effective date that is other than the first day of a month.

Also, there are significant costs to the Copyright Office associated with implementing the new rates. New statement of account forms must be created and sent to satellite carriers, and staff must be trained to examine for application of the new rates. The Register notes that satellite statements of account for the second accounting period of 1997 are due to be filed no later than January 30, 1998. 27 CFR 201.11(c). An effective date in the second accounting period of 1997 would cause significant burden and hardship to the Copyright Office to prepare to collect royalties and issue and process statements of account generated by the new royalty fees by the January 30, 1998, due date. Consequently, the Register recommends that the new royalty rates, adopted in today's decision, not be effective until January 1, 1998.

In recommending a January 1, 1998, effective date, the Register draws support from section 119(c)(3)(C). As discussed above, Congress apparently contemplated the possibility of the issuance of a final decision in this proceeding before (perhaps even well before) July 1, 1997. Congress could have chosen simply to make the decision effective on the date of adoption, but instead chose July 1, 1997, as the later effective date. July 1 is the first day of an accounting period which, has the final decision issued on or before that date, would have allowed the Copyright Office ample time to prepare for implementation of the new rates. Because today's decision is issuing only two months from the end of the 1997/2 accounting period, a January 1, 1998, effective date is consistent with Congressional intent.

The parties have raised two other issues, discussed above, which the Register briefly addresses. First, SBCA alleges that because initiation of the CARP was delayed 2 months to enable the Librarian to rule on the matter of whether local retransmissions should be a part of this proceeding, the entire proceeding is invalid. The Register agrees with Copyright Owners that the cases cited by SBCA for this rather remarkable contention are inapposite. *United States* v. *Amdahl Corp.*, 786 F.2d 387 (Fed. Cir. 1986) involved a contract entered into by the Treasury Department that was statutorily outside the scope of its authority. Contracting outside the scope of authority differs significantly from postponing procedural dates for good cause. *Albenga* v. *Ward*, 635 F. Supp. 660 (S.D.N.Y. 1986) involved an agency that created rules beyond its authority. Again, this is significantly different. Finally, *Baumgardner* v. *Secretary, Dept. of Housing and Urban Development*, 960 F.2d 572 (6th Cir. 1992) involved the failure of an agency to timely deliver an accurate complaint. As SBCA notes, the court in this case did not find the agency action invalidated because the delay was not sufficiently prejudicial. The Register cannot find any convincing evidence of irreparable prejudice incurred by SBCA as a result of the brief delay, particularly where the Register is recommending a January 1, 1998, effective date.

Furthermore, the Register notes that the same claim of invalidity has been raised in a Copyright Royalty Tribunal proceeding, and expressly rejected by the D.C. Circuit. The Court stated: ''It would be irrational and wholly unprecedented for a court to direct an agency to scrap a year's hearings and decisionmaking effort and start over because its proceeding did not conclude precisely on time.'' *National Cable Television Ass'n, Inc.* v. *CRT*, 724 F.2d 176, 189 n. 23 (D.C. Cir. 1983). The Register agrees with this view, and recommends rejection of SBCA's argument.

Second, in support of its position that satellite carriers would be unduly harmed by a July 1, 1997, effective date, SBCA submitted affidavits of satellite

[16] Ms. McLaughlin's testimony was based upon her projection of what the average cable network license fees would be for 1997 (26 cents), 1998 (27 cents) and 1999 (28 cents), not the actual figures. *Id.* at 19.

representatives. Copyright Owners moved to strike these affidavits, and SBCA opposed. The Register's recommendation of a January 1, 1998, effective date has mooted the issue. The Register does recommend, however, that the affidavits be stricken. The record is closed in this proceeding by order of August 14, 1997, section 251.55 does not permit submission of additional evidence. Although the matter of the effective date is for the Librarian, and not the CARP, to decide, such affidavits could only be accepted if the Librarian determined that the record needed to be reopened to take additional testimony. Since the matters discussed in SBCA's affidavits are moot, the Register recommends that they be stricken.

*G. Additional Issues Raised by SBCA*

SBCA raises several additional issues in its Petition to Modify. Because these issues all relate to evidence not adduced during the course of the proceeding, and the weight to be accorded evidence that was adduced, they are addressed together.

1. The first issue involves the history of retransmission consent negotiations under the communications law. Under retransmission consent, an MVPD must obtain the permission of a broadcaster before the MVPD can retransmit the broadcaster's signal to the MVPD's subscribers. Retransmission consent negotiations took place between the cable industry and broadcasters in 1993 and 1996. SBCA attempted to show that little compensation was obtained by broadcasters for permission to retransmit their signals in an effort to prove that the fees under the section 111 license represent actual fair market value. The Panel stated that ''[w]e agree that these retransmission consent negotiations are relevant to a determination of fair market value and represent potentially probative evidence. Unfortunately, the evidence adduced is so vague and replete with qualifiers as to provide little guidance.'' Panel Report at 34. The Panel noted cross-examination testimony of Ms. McLaughlin and Mr. Gerbrandt indicating that some compensation was paid, but also noted that Mr. Shooshan's and Mr. Haring's testimony discussed retransmission consent negotiations only in the context of local, and not distant, retransmissions. *Id.* at 35. The Panel concluded that the ''testimony upon which SBCA relies lacks sufficient scope and specificity to rebut or modify the PBS-McLaughlin analysis.'' *Id.*

SBCA submits that it could not present further evidence on the compensation received by copyright owners and broadcasters for retransmission consent negotiations because ''discovery procedures do not allow the Carriers to determine those amounts.'' SBCA Petition to Modify at 35. SBCA asserts that the failure to present such information ''should not be then turned against the Carriers to say that the retransmission consent negotiations cannot be properly quantified.'' *Id.*

Copyright Owners contend that the Panel correctly evaluated the evidence of retransmission consent negotiations and found it unavailing in making an adjustment to the benchmark. Copyright Owners Reply at 27–31.

2. The second issue involves the issue of the costs incurred by cable networks in assembling the clearances for their programming. SBCA attempted to show at hearing that copyright owners do not have costs in the broadcast signal retransmission context, and therefore an appropriate downward adjustment of the benchmark must be made. The Panel stated that the clearance costs in the cable network arena are unknown, but did not agree that a downward adjustment of the benchmark was required:

> In a hypothetical free market, it is quite conceivable that the higher the costs broadcasters must pay to clear their signals for DTH[17] distribution, the higher the royalty rates they would charge satellite carriers. Accordingly, the impact of high clearance costs on fair market value (based upon a hypothetical free market analysis) could be positive rather than negative. No adjustment to the cable network benchmark is required.

Panel Report at 41.

SBCA argues that it could not determine the costs to copyright owners for clearances of cable networks since such information was not within the scope of discovery, and therefore one should not assume, as the Panel did, that such costs could automatically be shifted to satellite carriers. SBCA Petition to Modify at 30.

Likewise, SBCA argues that it could not quantify at hearing the added benefit that satellite retransmission gives copyrighted programming (digital picture quality, inclusion in electronic guides) because of ''the absence of any ability to take discovery.'' *Id.* at 31–32. The Panel determined that ''no quantifiable benefit was identified and no evidence adduced'' to demonstrate added value by satellite retransmission.'' Panel Report at 40. SBCA asserts that ''the Panel held the Carriers to an unworkable standard of proof.'' SBCA Petition to Modify at 32.

In reply, Copyright Owners contend that the Panel acted correctly. Copyright Owners Reply at 24–27.

3. A third issue involves quantifying the effect on advertising revenues and superstation fees of satellite retransmissions of broadcast signals. SBCA asserts that they quantified ''as well as could be in a regime which denies discovery'' that advertising revenues are higher because copyright owners known that their programming reaches a wider audience due to satellite retransmission. SBCA Petition to Modify at 36. Likewise, SBCA asserts that ''superstation taxes''—the amounts charged to broadcasters by copyright owners—are greater, particularly in the sports context, because copyright owners know that satellite retransmissions result in greater viewership. *Id.* at 37–38. SBCA presented evidence that both the professional baseball and basketball leagues extracted additional compensation from WGN in Chicago and WTBS in Atlanta—both superstations known to be widely distributed on satellite—though the amount was not quantified. SBCA Proposed Findings of Fact and Conclusions of Law at 72–73.

The Panel addressed the potential for increased advertising revenue due to satellite retransmissions, stating:

> The fundamental mission of broadcasters is to expand their audiences to maximize advertising revenues. At their own expense and risk, the satellite carriers developed a DTH market which expands the broadcasters [sic] reach at no cost to the broadcasters. However, we agree that no empirical evidence demonstrating an increase in advertising revenues was adduced. Though the broadcasters (and hence the copyright owners) clearly benefit from expanded reach, these benefits may not be amenable to measurement and quantification. The copyright owners further argue that because most basic cable networks also advertise, to the extent that broadcasters to benefit from expanded reach, the benefit is already reflected in the cable network benchmark. We agree *to a point*. Broadcast stations rely upon advertising revenue to a much greater extent than do cable networks (excepting those cable networks which command very low or even negative royalty fees). It naturally follows that the benefits which accrue to broadcasters have *not* been *fully* reflected in the cable network benchmark price. Though some downward adjustment from the copyright owners *general* approach seems appropriate, we are unable to quantify such an adjustment. However, our decision to adopt the most conservative approach (PBS-McLaughlin) reflects this consideration.

Panel Report at 36–37. The Panel did not use the term ''superstation tax'' in its discussion.

[17] ''DTH'' stands for ''direct to home.''

SBCA complains that the Panel ignored its evidence of increased revenues from satellite retransmissions, and that it is ''no excuse that the [o]wners refused to divulge the extent of the compensation.'' SBCA Petition to Modify at 38. SBCA asserts that not subtracting this added value from the benchmark would result in ''vastly overcompensat[ing]'' copyright owners. *Id*.

In reply, Copyright Owners assert that the Panel correctly determined that, while such revenues might conceptually result in a downward adjustment, SBCA failed to quantify such an adjustment. Copyright Owners Reply at 31.

4. The fourth issue concerns the impact of increased royalty fees on the satellite industry and the continued availability of retransmitted broadcast signals. The Panel accepted Ms. McLaughlin's testimony that the 27 cent fee would not significantly adversely impact satellite:

> Although Ms McLaughlin did not perform a demand elasticity study, she testified that after the 1992 rate increases, the number of broadcast stations retransmitted and the percentage of satellite subscribers to retransmitted broadcast signals remained constant. She concluded that despite an increase in the compulsory license rate to $0.27 per subscriber per month, the number of subscribers to retransmitted broadcast stations would continue to grow at substantially the same rate as the number of satellite subscribers generally. Ms. McLaughlin also examined the retail prices charged by satellite distributors and concluded that if the rates for retransmitted broadcast signals were increased to $0.27 per subscriber per month and *not* passed on to subscribers, those rates would constitute only 30% of the average retail prices charged to subscribers leaving sufficient profit margin for the satellite carriers to avoid significant adverse impact to them or their subscribers.
>
> Again, we recognize that *any* rate increase, particularly if rates are set above those paid by their entrenched competitor, tends to adversely impact the satellite carriers. However, the satellite carriers did not attempt to quantify the impact of increased rates and adduced no credible evidence that the availability of secondary transmissions would be interrupted. Accordingly, we conclude that a rate increase to $0.27 per subscriber per month would have no significant adverse impact upon the satellite carriers or the availability of secondary transmissions to the public.

Panel Report at 46–47 (citations omitted).

SBCA contends that the Panel had no evidence upon which to base its conclusion that a dramatic rate increase would not adversely affect satellite carriers and their subscribers. SBCA Petition to Modify at 42. Rather, SBCA asserts, the evidence, including that relied upon by Ms. McLaughlin, ''shows that satellite carriers have yet to earn a profit, especially in the DBS market, and that the C-Band market is waning.'' *Id*. SBCA notes that Ms. McLaughlin did not perform a demand elasticity analysis for increased rates, and that her testimony that the 1992 rate increase did not impact subscriptions or the number of signals carried was not based upon anything in the record. *Id*. at 42–43. SBCA also mentions that the 1992 panel reduced its initial rate increase because of a concern for disruptive impact. 57 FR 19061.

SBCA also charges that the Panel ignored its evidence regarding the disruptive impact of a rate increase. It points to the testimony of Mr. Parker who stated that there is a limit on the package rate to be charged consumers, and that satellite carriers have traditionally gone back to cable networks to demand concessions in order to keep prices down. SBCA Petition to Modify at 44. SBCA argues that any increases in the rates should be examined in light of the impact lower fees would have on copyright owners. According to SBCA, there is no evidence that suggests that the current fees of section 119 have any adverse impact on the copyright and broadcast industries. *Id*. at 45.[18]

In reply, Copyright Owners assert that it was completely within the discretion of the Panel to accord weight to Ms. McLaughlin's testimony that satellite carriers would not be adversely impacted by the increased royalty rates. Copyright Owners Reply at 36. Copyright Owners argue that Mr. Parker's testimony is nonspecific, and that the testimony of Mr. Edwin Desser and Mr. James Trautman show that satellite carriers are owned by large corporate enterprises that can well afford the proposed rate increase. *Id*. at 39–40.

**Recommendation of the Register**

The Register is addressing these four arguments presented by SBCA together because they contain a common thread: the absence of evidence adduced before the Panel and, where evidence was produced, the weight and sufficiency to be accorded it.

Given the limited scope of the Librarian's review in this proceeding, ''the Librarian will not second guess a CARP's balance and consideration of the evidence, unless its decision runs completely counter to the evidence presented to it.'' 61 FR 55663 (Oct. 28, 1996) (citing *Motor Vehicle Manufacturers Ass'n* v. *State Farm Mutual Auto Insurance Co*., 463 U.S. 29, 43 (1983). In the case of the impact of a rate increase on the satellite industry, the Panel chose to accord weight to Ms. McLaughlin's testimony that her proposed rate increase would not adversely affect the satellite industry, rather than Mr. Parker's testimony. It was clearly within the Panel's discretion to do so. There is record testimony that supports the Panel's conclusion, and the Librarian's review need go no further. *Recording Industry Ass'n of America, Inc*. v. *CRT*, 662 F.2d 1, 14 (D.C. Cir. 1981) (decision must be upheld where decisionmaker's path may reasonably be discerned).

The remaining issues contested by SBCA—the impact of retransmission consent negotiations, added value from digital picture/electronic guides and avoidance of clearance costs, and increased advertiser revenue and compensation from expanded markets—predominately involve the matter of evidence not presented to the CARP. In essence, SBCA contends that if the discovery rule of 37 CFR 251.45(c)(1) were broader, if could have presented evidence to the Panel on these issues that would have caused the Panel to reduce the 27 cent royalty fee. Instead, according to SBCA, the Panel punished it for failure to present the necessary evidence to quantify the reductions, and the 27 cent rate, consequently, is unfairly high.

Section 251.45(c)(1) of the rules provides that, after the exchange of the written direct cases, a party ''may request of an opposing party nonprivileged underlying documents related to the written exhibits and testimony.'' 37 CFR 251.45(c)(1). The Librarian has clarified that discovery is limited in CARP proceedings:

> Discovery in CARP proceedings is intended to produce only the documents that underlie the witness' factual assertions. It is not intended to augment the record with what the witness might have said or put forward, or to range beyond what the witness said. Any augmentation of the record is the prerogative of the arbitrators, not the parties.

Order in Docket No. 94–3 CARP CD 90–92, 1–2 (October 30, 1995). There are several reasons for the limited discovery practice. CARP proceedings are relatively short in duration (180 days) and, like this proceeding, begin and end according to statutorily specified deadlines. There is not sufficient time to conduct wide-ranging discovery,

[18] Regarding the economic impact of royalty fees on copyright owners, the Panel stated that ''[t]he parties devoted little hearing time to this issue.'' Panel Report at 46. The Panel did ''accept the obvious, general notion that higher royalty rates provide greater incentive to copyright owners while lower rates would render broadcast stations a '* * * less attractive vehicle at the margin for program supplies.'' *Id*. (citation omitted).

particularly where, as in the case, the litigation is quite complex and involves the technically-oriented testimony of numerous witnesses. There are also cost considerations. Broad discovery rules would considerably increase the cost of CARP proceedings, without necessarily producing a corresponding increase in the quality of the evidentiary presentations. The parties may, therefore, as of right only request documents which underlie a witness's factual assertions.

The rules do not, however, prohibit a party, once the CARP has begun, from petitioning the Panel to take discovery on an issue or issues that it believes are critical to the resolution of the proceeding. As noted above, augmentation of the record is the prerogative of the CARP, and the Panel has the discretion to decide whether or not to allow additional discovery beyond that of section 251.45(c)(1). *See* 37 C.F.R. 251.42 (CARP may waive the rules upon a showing of good cause). SBCA complains that the Panel might have reduced the royalty rates based on the issues it raised had it allowed additional discovery. Yet, SBCA never petitioned the Panel to take such discovery. The Panel cannot be faulted for not reopening the record and allowing additional discovery when it was asked to do so. *See National Ass'n of Broadcasters* v. *CRT*, 772 F.2d 922, 936–937 (D.C. Cir. 1985) (claimant failed to petition Tribunal to allow it to adduce additional evidence regarding opposing party's alleged lack of copyright ownership).

The issue remains as to whether the Panel should have reopened the record, on its own motion, and allowed SBCA to take discovery on the issues it rates: i.e. whether it was arbitrary for the Panel not to do so. In the Register's view, the Panel did not act arbitrarily. Regarding the value of retransmission consent negotiations, the Panel found that Ms. McLaughin, and Messrs. Gerbrandt, Shooshan and Harin offered testimony regarding the probative value of retransmission consent negotiations on the fair market value of retransmitted broadcast signals. Panel Report at 34–35. The Panel found this testimony to be unsupportive of the proposition that retransmission consent negotiations affected the fair market value analysis. *Id*. at 35. Because there is record evidence to support the Panel's determination, the Panel did not act arbitrarily.

With regard to the purported added value to broadcast signals by satellite retransmission in digital format, and attractive electronic guides provided the subscribers, the Panel determined that ''no quantifiable benefit was identified and no evidence adduced that this benefit would materially affect fair market value * * *.'' Panel Report at 40. As the Copyright Owners correctly point out, any added value from digital picture quality and electronic guides would occur for both broadcast and cable network programming. Copyright Owners Reply at 25. SBCA could have presented evidence that demonstrated that satellite carriers pay a lower fee for licensing cable networks as a result of digital picture quality and electronic guides provided by the carriers. Such evidence, if it exists, is in the sole possession of the satellite carriers. SBCA presented no such evidence. The Panel, therefore, cannot be faulted from finding no evidence to support added value from these items.

Regarding clearance costs saved by broadcasters and copyright owners from satellite retransmissions, the Panel stated:

> SBCA further argues that in a free market, it would be virtually impossible for satellite carriers to negotiate directly with every copyright owner of every program contained in each day's signal they retransmit. Accordingly, they reason, broadcasters would invariably by compelled by market forces to clear all rights and negotiate with satellite carriers for retransmission of their entire signals. Those costs which the broadcasters would incur in purchasing the clearances are unknown. Hence, SBCA concludes that the section 119 rates should not be raised without considering the broadcasters' cost savings. We tend to agree with both of SBCA's premises but not its conclusion. In a hypothetical free market, it is quite conceivable that the higher the costs broadcasters must pay to clear their signals for DTH distribution, the higher the royalty rates they would charge satellite carriers. Accordingly, the impact of higher clearance costs on the fair market value (based upon a hypothetical free market analysis) could be positive rather than negative. No adjustment to the cable network benchmark is required.

Panel Report at 41.

SBCA contends that Copyright Owners never put on any evidence demonstrating their cost savings, and it should not therefore be presumed that clearance costs would be passed on to satellite carriers. SBCA Petition to Modify at 30. SBCA's argument, however, is one of emphasis rather than evidence. SBCA asked the Panel to quantify what the average cost *might* be, in a *hypothetical market,* for clearance costs, and how satellite carriers and broadcasters *might* allocate such costs. Not surprisingly, SBCA does not indicate what, if any evidence, would conclusively demonstrate what such costs might be, or who might bear them.[10] It is not reversible error for the Panel to reason that in a marketplace which does not exist, clearance costs might have a positive effect on the cable network benchmark, rather than a negative one.[20]

Finally, with regard to the purported increase in advertising revenues and compensation from expanding coverage of broadcast signals by satellite retransmission, the Panel found that it could not quantify any potential reductions of the cable network benchmark. Panel Report at 37. While allowing SBCA expanded discovery on these points might have assisted the Panel in quantifying a downward adjustment to the cable network benchmark, the Register cannot determine anything in the record that compelled it. Furthermore, the Panel did conclude that its choice of the ''conservative'' PBS/McLaughlin cable network benchmark reflected its inability to quantify any increased advertising revenues that copyright owners might receive from expanded markets through satellite retransmission. *Id*. In the Register's view, the Panel's action was the product of rational decisionmaking.

*H. Conclusion*

Having fully analyzed the record in this proceeding and considered the contentions of the parties, the Register recommends that the Librarian of Congress adopt the royalty rate, effective January 1, 1998, of 27 cents per subscriber per month for retransmission of any distant superstation and network signals by satellite carriers to subscribers for private home viewing.

In addition, the Register recommends that the Librarian not adopt any royalty fee for the local retransmission of superstation signals, as defined under 17 U.S.C. 119(d)(11), and for the local retransmission of a network signal, as defined under § 119(d)(11), to any subscriber residing in an unserved household, as defined in § 119(d)(10).

Finally, the Register recommends that the petition to modify the Panel's decision filed by EchoStar be dismissed, and the motion of Copyright Owners to dismiss attachment A of SBCA's petition to modify (and the

[19] SBCA does cite a statement of FCC Commissioner Dennis that broadcasters might have to bear these costs. SBCA Petition to Modify at 30 (citing ''In re Compulsory Copyright License for Cable Retransmissions,'' 4 FCC Rcd. 6711 (1989) (Commissioner Dennis, concurring). However, Commissioner Dennis' statement is speculative, describing what might happen to broadcasters ''in some cases,'' 4 FCC Rcd. at 6711, and is far from conclusive evidence.

[20] In fact, the Panel did not make any change to the benchmark for clearance costs.

accompanying argument and discussion) be granted.

**Order of the Librarian**

Having duly considered the recommendation of the Register of Copyrights regarding the Report of the Copyright Arbitration Royalty Panel in the matter of the adjustment of the royalty rates for the satellite carrier compulsory license, 17 U.S.C. 119, the Librarian of Congress fully endorses and adopts here recommendation to accept the Panel's decision in part and reject it in part. For the reasons stated in the Register's recommendation, the Librarian is exercising his authority under 17 U.S.C. 802(f) and is issuing this order, and amending the rules of the Library and the Copyright Office, announcing the new royalty rates for the section 119 compulsory license.

The Librarian is also dismissing the petition to modify filed by EchoStar, and is dismissing the affidavits contained in attachment A of SBCA's petition to modify, and the accompanying discussion and argument.

**List of Subjects in 37 CFR Part 258**

Copyright, Satellites, Television.

**Final Regulation**

In consideration of the foregoing, the Library of Congress amends part 258 of 37 CFR as follows:

## PART 258—ADJUSTMENT OF ROYALTY FEE FOR SECONDARY TRANSMISSIONS BY SATELLITE CARRIERS

1. The authority citation for part 258 continues to read as follows:

**Authority:** 17 U.S.C. 702, 802.

2. Section 258.3 is revised to read as follows:

**§ 258.3 Royalty fee for secondary transmission of broadcast stations by satellite carriers.**

(a) Commencing May 1, 1992, the royalty rate for the secondary transmission of broadcast stations for private home viewing by satellite carriers shall be as follows:

(1) 17.5 cents per subscriber per month for superstations.

(2) 14 cents per subscriber per month for superstations whose signals are syndex-proof, as defined in § 258.2.

(3) 6 cents per subscriber per month for network stations and noncommercial educational stations.

(b) Commencing January 1, 1998, the royalty fee for secondary transmission of broadcast stations for private home viewing by satellite carriers shall be as follows:

(1) 27 cents per subscriber per month for distant superstations.

(2) 27 cents per subscriber per month for distant network stations.

(3) No royalty rate (zero) for a superstation secondarily transmitted within the station's local market, as defined in 17 U.S.C. 119(d)(11).

(4) No royalty rate (zero) for a network station secondarily transmitted within the station's local market, as defined in 17 U.S.C. 119(d)(11), to subscribers residing in unserved households, as defined in 17 U.S.C. 119(d)(10).

Dated: October 23, 1997.
*So Ordered.*

**James H. Billington,**
*The Librarian of Congress.*

[FR Doc. 97–28543 Filed 10–27–97; 8:45 am]
BILLING CODE 1410–33–M

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## DEPARTMENT OF DEFENSE

## DEPARTMENT OF TRANSPORTATION

## Coast Guard

## DEPARTMENT OF VETERANS AFFAIRS

## 38 CFR Part 21

**RIN 2900–AI69**

## Miscellaneous Educational Revisions

**AGENCIES:** Department of Defense, Department of Transportation (Coast Guard), and Department of Veterans Affairs.

**ACTION:** Final rule.

**SUMMARY:** This document amends the educational assistance and educational benefit regulations of the Department of Veterans Affairs (VA). It removes a number of provisions that no longer apply or otherwise have no substantive effect, and makes other changes for the purpose of clarification.

**DATES:** This final rule is effective October 28, 1997.

**FOR FURTHER INFORMATION CONTACT:** June C. Schaeffer, Assistant Director for Policy and Program Administration, Education Service, Veterans Benefits Administration, 202–273–7187.

**SUPPLEMENTARY INFORMATION:** This document affects 38 CFR part 21, subparts C, D, G, H, K, and L. It removes provisions that are obsolete, duplicative, or otherwise without substantive effect, and makes changes for the purpose of clarification. This document makes no substantive changes. Accordingly, there is a basis for dispensing with prior notice and comment and delayed effective date provisions of 5 U.S.C. 552 and 553.

The Department of Defense (DOD) and VA are jointly issuing this final rule insofar as it relates to the Post-Vietnam Era Educational Assistance Program (VEAP) and the Educational Assistance Test Program (EATP). These programs are funded by DOD and administered by VA. DOD, the Department of Transportation (Coast Guard), and VA are jointly issuing this final rule insofar as it relates to the Montgomery GI Bill—Selected Reserve program. This program is funded by DOD and the Coast Guard, and is administered by VA. The remainder of this final rule is issued solely by VA.

The Secretary of Defense, the Commandant of the Coast Guard, and Acting Secretary of Veterans Affairs hereby certify that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This final rule makes no substantive changes. Pursuant to 5 U.S.C. 605(b), this final rule, therefore, is exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604.

The Catalog of Federal Domestic Assistance numbers for programs affected by this final rule are 64.117, 64.120, and 64.124. This document also affects the Montgomery GI Bill—Selected Reserve program which has no Catalog of Federal Domestic Assistance number.

**List of Subjects in 38 CFR Part 21**

Administrative practice and procedure, Armed forces, Civil rights, Claims, Colleges and universities, Conflict of interests, Education, Employment, Grant programs-education, Grant programs-veterans, Health care, Loan programs-education, Loan programs-veterans, Manpower training programs, Reporting and recordkeeping requirements, Schools, Travel and transportation expenses, Veterans, Vocational education, Vocational rehabilitation.

Approved: July 22, 1997.

**Hershel W. Gober,**

*Acting Secretary of Veterans Affairs.*

Approved: October 2, 1997.

**Allan L. Brendsel,**

*Colonel USA, Principal Deputy, Deputy Assistant Secretary (Military Personnel Policy).*

Approved: October 9, 1997.

**G.E. Woolever,**

*Rear Admiral, U.S. Coast Guard, Assistant Commandant for Human Resources.*

For the reasons set forth in the preamble, 38 CFR part 21, subparts C, D, G, H, K, and L, is amended as set forth below.

## PART 21—VOCATIONAL REHABILITATION AND EDUCATION

### Subpart C—Survivors' and Dependents' Educational Assistance under 38 U.S.C. Chapter 35

1. The authority citation for part 21, subpart C, continues to read as follows:

**Authority:** 38 U.S.C. 501(a), 512, 3500–3566, unless otherwise noted.

**§ 21.3041 [Amended]**

2. In § 21.3041, paragraph (e)(3) is amended by removing ''§ 21.4135(o)'' and adding, in its place, ''§ 21.3135(h)''; and paragraph (e)(4) is amended by removing ''§ 21.4135(o)'' and adding, in its place, ''§ 21.3135(i)''.

3. In § 21.3045, paragraph (i)(3)(ii) is amended by removing ''paragraph (h)(3)(i)'' and adding in its place, ''paragraph (i)(3)(i)''; and paragraph (f) is revised to read as follows:

**§ 21.3045 Entitlement charges.**

* * * * *

(f) *Entitlement charge for pursuit solely by independent study.* For enrollments in terms, quarters, or semesters that begin after June 30, 1993, VA will make charges against the entitlement of an eligible person in the manner prescribed by paragraph (e) of this section, if he or she is pursuing a program of education solely by independent study. For all other enrollments where the eligible person is pursuing a program of education solely by independent study, the computation will be made as though the eligible person's training were one-quarter time.

(Authority: 38 U.S.C. 3482(b), 3532(a))

* * * * *

### Subpart D—Administration of Educational Assistance Programs

4. The authority citation for part 21, subpart D, is revised to read as follows:

**Authority:** 10 U.S.C. ch. 1606; 38 U.S.C. 501(a), chs. 30, 32, 34, 35, 36, unless otherwise noted.

**§ 21.4009 [Amended]**

5. In § 21.4009, paragraph (b)(1) introductory text, is amended by removing ''in potentially'' and adding, in its place, ''is potentially''.

6. In § 21.4200, paragraph (g) is revised to read as follows:

**§ 21.4200 Definitions.**

* * * * *

(g) *Standard class session.* The term *standard class session* means the time an educational institution schedules for class each week in a regular quarter or semester for one quarter or one semester hour of credit. It is not less than 1 hour (or one 50-minute period) of academic instruction, 2 hours (or two 50-minute periods) of laboratory instruction, or 3 hours (or three 50-minute periods) of workshop training.

(Authority: 38 U.S.C. 3688(c))

* * * * *

**§ 21.4201 [Amended]**

7. In § 21.4201, paragraph (h) introductory text is amended by removing ''Vocational Rehabilitation and'' both times it appears; and paragraph (h)(2) is amended by removing ''Vocational Rehabilitation and''.

**§ 21.4233 [Amended]**

8. In § 21.4233, paragraph (b)(3) introductory text is amended by removing ''(b)(1)'' and adding, in its place, ''(b)(2)''; paragraph (b)(3)(ii) is amended by removing ''(b)(2)(i)'' and adding, in its place, ''(b)(3)(i)''; paragraph (b)(4) introductory text is amended by removing ''(b)(1)'' and adding, in its place, ''(b)(2)''; and paragraph (b)(4)(ii) is amended by removing ''(b)(3)(i)'' and adding, in its place, ''(b)(4)(i)''.

**§ 21.4250 [Amended]**

9. In § 21.4250, paragraph (a)(1) is amended by removing ''Chapter'' and adding, in its place, ''38 U.S.C. chapter'', and by removing ''Chapters 34 and'' and adding, in its place, ''38 U.S.C. chapter''; paragraph (a)(2) is amended by removing ''Chapter'' each place it appears, and adding, in its place, ''38 U.S.C. chapter''; paragraph (c)(1) is amended by removing ''Director'' and adding, in its place, ''Director,'', by removing ''Education'' and adding, in its place, ''Counseling'', and by removing ''Chapter'' and adding, in its place, ''38 U.S.C. chapter''; paragraph (c)(2) is amended by removing ''Vocational Rehabilitation and''; paragraph (c)(2)(ii) is amended by removing ''34, 35'' and adding, in its place ''35,''; paragraph (c)(2)(iii) is amended by removing ''38 U.S.C. Chapter 32, 34 or 35'' and adding, in its place, ''10 U.S.C. chapter 1606 or 38 U.S.C. chapter 30, 32, or 35''; and paragraph (c)(2)(iv) is amended by removing ''Chapter'' and adding, in its place, ''chapter''.

10. In § 21.4270, the heading for paragraph (c) and paragraph (c), footnote 2 are revised to read as follows:

**§ 21.4270 Measurement of courses.**

* * * * *

(c) *Undergraduate, graduate, professional, and on-the-job training courses.** * *

[2] When the institution certifies that all undergraduate students enrolled for a minimum of 12 or 13 semester hours or the equivalent are charged full-time tuition, or considered full time for other administrative purposes, such minimum hours will establish the criteria for full-time measurement. When 12 hours is properly certified as full time, VA will measure 9 through 11 hours as ¾ time, 6 through 8 hours as ½ time, 4 through 5 hours as less than ½ time and more than ¼ time, and 1 through 3 hours as ¼ time or less. VA will measure all other undergraduate courses as indicated in the table for undergraduate or professional courses, as appropriate, but when 13 credit hours or the equivalent is certified as full time, ¾ time will be 10 through 12 hours. When, in accordance with § 21.4273(a), a responsible official of a school certifies that a lesser number of hours constitute full time, ¾ time, ½ time, less than ½ time and more than ¼ time, or ¼ time or less, VA will accept the certification for measurement purposes.

To meet criteria for full-time measurement in standard collegiate courses which include required noncredit deficiency courses, in the absence of a certification under § 21.4272(k), VA will convert the noncredit deficiency courses on the basis of the applicable measurement criteria, as follows: 18 or 22 clock hours, 4 ''Carnegie Units,'' or 12, 13, or 14 (as appropriate) semester hours equal full time. The credit-hour equivalent of such noncredit courses may constitute any portion of the required hours for full-time measurement.

* * * * *

### Subpart G—Post Vietnam Era Veterans' Educational Assistance Under 38 U.S.C. Chapter 32

11. The authority citation for part 21, subpart G, is revised to read as follows:

**Authority:** 38 U.S.C. 501(a), ch. 32, unless otherwise noted.

**§ 21.5270 [Amended]**

12. In § 21.5270, paragraph (a) is amended by removing ''of this part'' and by removing ''chapter'' and adding, in its place, ''38 U.S.C. chapter''; paragraph (g) is amended by removing ''progress and conduct'' and adding, in its place,

''progress, conduct, and attendance''; and paragraph (i) is amended by removing ''correspondence; residence'' and adding, in its place ''correspondence-residence''.

## Subpart H—Educational Assistance Test Program

13. The authority citation for subpart H is revised to read as follows:

**Authority:** 10 U.S.C. ch. 107; 38 U.S.C. 501(a), 3695, 5101, 5113, 5303A; 42 U.S.C. 2000; sec. 901, Pub. L. 96–342, 94 Stat. 1111–1114, unless otherwise noted.

### § 21.5901 [Amended]

14. In § 21.5901, paragraph (a) is amended by removing ''Chief Benefits Director of VA'' and adding, in its place, ''Under Secretary for Benefits'', by removing ''Vocational Rehabilitation and'', and by removing ''Chapter'' and adding, in its place, ''chapter'; and paragraph (b) is amended by removing ''Chief Benefits Director'' and adding, in its place, ''Under Secretary for Benefits''.

## Subpart K—All Volunteer Force Educational Assistance Program (Montgomery GI Bill—Active Duty)

15. The authority citation for subpart K is revised to read as follows:

**Authority:** 38 U.S.C. 501(a), chs. 30, 36, unless otherwise noted.

16. In § 21.7020, the introductory text is amended by removing ''of this part''; paragraph (a)(1)(i) is amended by removing ''of this part''; paragraph (a)(2)(i) is amended by removing ''§ 21.7042 or § 21.7044 of this part'' and adding, in its place, ''§ 21.7042, § 21.7044, or § 21.7045''; and paragraph (b)(25)(i)(G) is revised to read as follows:

### § 21.7020 Definitions.

* * * * *

(b) * * *

(25) * * *

(i) * * *

(G) A flight training course beginning on or after September 30, 1990.

* * * * *

### § 21.7044 [Amended]

17. In § 21.7044, paragraph (c) is removed; and paragraphs (d) and (e) are redesignated as paragraphs (c) and (d), respectively.

18. In § 21.7140, paragraph (c)(1)(iii) is removed; paragraph (c)(1)(i) is amended by removing ''§ 21.7152;'' and adding, in its place, ''§ 21.7152; and''; paragraph (c)(1)(ii) is amended by removing ''enrollment; and'' and adding, in its place, ''enrollment.''; paragraph (d)(1) is amended by removing ''Ch.'' and adding, in its place, ''chapter'', and by removing ''in the same manner as they are applied in the administration of chapter 34''; paragraph (e)(2) is amended by removing, ''in the same manner as they are applied in the administration of chapters 34 and 36''; and the authority citations for paragraphs (c)(1), (d), (e), and (g) are revised to read as follows:

### § 21.7140 Certifications and release of payments.

* * * * *

(c) * * *

(1) * * *

(Authority: 38 U.S.C. 3680(g))

* * * * *

(d) * * *

(Authority: 38 U.S.C. 3034, 3680)

(e) * * *

(Authority: 38 U.S.C. 3034, 3680)

(g) * * *

(Authority: 38 U.S.C. 5121)

19. Section 21.7144 is revised to read as follows:

### § 21.7144 Overpayments.

(a) *Prevention of overpayments.* In administering benefits payable under 38 U.S.C. chapter 30, VA will apply the provisions of § 21.4008. See § 21.7133.

(Authority: 38 U.S.C. 3034, 3690(b))

(b) *Liability for overpayments.* (1) The amount of the overpayment of educational assistance paid to a veteran or servicemember constitutes a liability of that veteran or servicemember.

(2) The amount of the overpayment of educational assistance paid to a veteran or servicemember constitutes a liability of the educational institution if VA determines that the overpayment was made as the result of willful or negligent:

(i) False certification by the educational institution; or

(ii) Endorsement of a veteran's or servicemember's false certification of his or her actual attendance.

(Authority: 38 U.S.C. 3034, 3685)

(c) *Recovery of overpayments.* In determining whether an overpayment should be recovered from an educational institution, VA will apply the provisions of § 21.4009 (except paragraph (a)(1)) to overpayments of educational assistance under 38 U.S.C. chapter 30.

(Authority: 38 U.S.C. 3034, 3685)

Cross reference: Entitlement charges. See § 21.7076(c).

21. Section 21.7170 is revised to read as follows:

### § 21.7170 Course measurement.

In administering benefits payable under 38 U.S.C. chapter 30, VA will apply the following sections:

(a) § 21.4270 (except paragraphs (a)(2) and (a)(3) and those portions of paragraph (c) and footnotes dealing with farm cooperative training)—Measurement of courses;

(b) § 21.4272—Collegiate course measurement;

(c) § 21.4273—Collegiate graduate;

(d) § 21.4274—Law courses; and

(e) § 21.4275—Practical training courses; measurement.

(Authority: 38 U.S.C. 3034, 3688)

21. In § 21.7172, paragraph (a)(3)(ii) is revised to read as follows:

### § 21.7172 Measurement of concurrent enrollments.

* * * * *

(a) * * *

(3) * * *

(ii) VA measures the courses pursued at the second school on a credit-hour basis, VA will convert the credit hours to clock hours to determine the veteran's training time.

(Authority: 38 U.S.C. 3034, 3688)

* * * * *

22. Section 21.7305 is revised to read as follows:

### § 21.7305 Conflicting interests.

In administering benefits payable under 38 U.S.C. chapter 30, VA will apply the provisions of § 21.4005.

(Authority: 38 U.S.C. 3034, 3036)

23. Section 21.7307 is revised to read as follows:

### § 21.7307 Examination of records.

In administering benefits payable under 38 U.S.C. chapter 30, VA will apply the provisions of § 21.4209.

(Authority: 38 U.S.C. 3034, 3690)

24. Section 21.7310 is revised to read as follows:

### § 21.7310 Civil rights.

(a) *Delegation of authority concerning Federal equal opportunity laws.* The Under Secretary for Benefits is delegated the responsibility to obtain evidence of voluntary compliance with Federal equal opportunity laws from educational institutions and from recognized national organizations whose representatives are afforded space and office facilities under his or her jurisdiction. See part 18 of this chapter. These equal opportunity laws are:

(1) Title VI, Civil Rights Act of 1964;

(2) Title IX, Education Amendments of 1972, as amended;

(3) Section 504, Rehabilitation Act of 1973; and

(4) The Age Discrimination Act of 1975.

(b) *Role of State approving agencies.* In obtaining evidence from educational institutions of compliance with Federal equal opportunity laws, the Under Secretary for Benefits may use the State approving agencies as provided in § 21.4258(d).

(Authority: 42 U.S.C. 2000)

## Subpart L—Educational Assistance for Members of the Selected Reserve

25. The authority citation for part 21, subpart L, continues to read as follows:

**Authority:** 10 U.S.C. ch. 1606; 38 U.S.C. 501(a), ch. 36, unless otherwise noted.

26. In § 21.7622, paragraph (c) is revised to read as follows:

### § 21.7622 Courses precluded.

* * * * *

(c) *Erroneous, deceptive, misleading practices.* VA will not pay educational assistance for an enrollment in any courses offered at an educational institution that uses advertising, sales, or enrollment practices that are erroneous, deceptive, or misleading by actual statement, omission, or intimation. VA will apply the provisions of § 21.4252(h) in making these decisions with regard to enrollments under 10 U.S.C. chapter 1606.

(Authority: 10 U.S.C. 16136(b); 38 U.S.C. 3696)

* * * * *

### § 21.7639 [Amended]

27. In § 21.7639, paragraph (b) introductory text is amended by removing ''As is the case with reservists who are not incarcerated,''.

28. Section 21.7659 is revised to read as follows:

### § 21.7659 Reporting fee.

In determining the amount of the reporting fee payable to educational institutions for furnishing required reports, VA will apply the provisions of § 21.4206.

(Authority: 10 U.S.C. 16136(b); 38 U.S.C. 3684)

### § 21.7670 [Amended]

29. In § 21.7670, paragraph (d) is amended by removing ''§ 21.4272(a), (b), (d), (e) (except paragraph (e)(4)), (f), (g), and (k)'' and adding, in its place, ''§ 21.4272''.

30. In § 21.7720, paragraphs (b)(9), (b)(10), and (b)(11) are redesignated as paragraphs (b)(11), (b)(12), and (b)(13), respectively; paragraph (b)(5) is amended by removing ''policy—nonaccredited'' and adding, in its place ''policy; nonaccredited''; newly redesignated paragraph (b)(11) is amended by removing ''(except paragraphs (a), (e), and (g))''; and paragraphs (b)(9) and (b)(10) are added to read as follows:

### § 21.7720 Course approval.

* * * * *

(b) * * *

(9) § 21.4261—Apprentice courses;

(10) § 21.4262—Other training on-the-job courses;

* * * * *

[FR Doc. 97–28402 Filed 10–27–97; 8:45 am]

BILLING CODE 8320–01–P

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## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Parts 52 and 64

**[CC Docket No. 92–237; FCC 97–386]**

## Administration of the North American Numbering Plan, Carrier Identification Codes (CICs)

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** On October 22, 1997, the Commission released an Order on Reconsideration addressing carrier identification codes (CICs). The Order on Reconsideration determines that by January 1, 1998 all local exchange carriers (LECs) that provide equal access must have completed switch changes to recognize four-digit CICs. The transition during which three and four-digit CICs co-exist will end on June 30, 1998. The Order on Reconsideration is intended to modify in part the decision in the CICs Second Report and Order (62 FR 19056, published April 18, 1997) regarding the length of the transition. The Commission concurrently released an Order on Application for Review and a second further notice of Proposed Rulemaking in the same docket.

**DATES:** Effective November 28, 1997.

**ADDRESSES:** Federal Communications Commission, Secretary, Room 222, 1919 M Street, NW., Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Nightingale, Attorney, Network Services Division, Common Carrier Bureau, (202) 418–2352.

**SUPPLEMENTARY INFORMATION:** This summarizes the Commission's Order on Reconsideration in the matter of Administration of the North American Numbering Plan, Carrier Identification Codes (CICs), CC Docket 92–237, adopted October 20, 1997, and released October 22, 1997. The file is available for inspection and copying during the weekday hours of 9 a.m. to 4:30 p.m. in the Commission's Reference Center, Room 239, 1919 M St., N.W., Washington D.C., or copies may be purchased from the Commission's duplicating contractor, ITS, Inc., 1231 20th Street, N.W., Washington, D.C. 20036, phone (202) 857–3800.

### Analysis of Proceeding

The Order on Reconsideration modifies the Commission's decision in the *CICs Second Report and Order* regarding the length of the transition during which three and four-digit Feature Group D CICs co-exist, and creates a ''two-step'' end to the transition. By January 1, 1998, the end of the first phase, all LECs that provide equal access must have completed switch changes to recognize four-digit CICs. The second phase, which ends on June 30, 1998, is intended to allow IXCs time to prepare their networks for, and educate their customers about, the replacement of three-digit CICs by four-digit CICs. After that date, only four-digit CICs and seven-digit carrier access codes (CACs) will be recognized. The Commission also affirms its decision in the *CICs Second Report and Order* not to grandfather the use of three-digit CICs and five-digit CACs that are in use during the transition. The Commission rejects arguments that the *CICs Second Report and Order:* (1) Is arbitrary and capricious in violation of the Administrative Procedure Act; (2) violates Fifth Amendment rights; (3) violates First Amendment rights; and (4) violates Section 257 of the Communications Act and the Regulatory Flexibility Act. The Commission's decisions in the Order on Reconsideration are intended to advance the pro-competitive objectives of the Communications Act, as amended.

### Ordering Clauses

2. Accordingly, *it is ordered,* pursuant to sections 1, 4(i), 201–205, and 251(e)(1) of the Communications Act of 1934, as amended, 47 U.S.C. §§ 151, 154(i), 201–205, and 251(e)(1), that the Petition for Reconsideration of VarTec Telecom, Inc., is *denied.*

3. *It is further ordered,* that the Petitions for Reconsideration of the Competitive Telecommunications Association and Telecommunications Group, Inc., *are granted* to the extent stated herein, and, in all other respects, *are denied.*

4. *It is further ordered,* that the Order on Reconsideration and the

requirements contained herein *will become effective* November 28, 1997. The collection of information contained within is contingent upon approval by the Office of Management and Budget.

**List of Subjects**

*47 CFR Part 52*

Local exchange carrier, Numbering, Telecommunications.

*47 CFR Part 64*

Communications common carriers, Telephone.

Federal Communications Commission.

**William F. Caton,**

*Acting Secretary.*

[FR Doc. 97–28555 Filed 10–27–97; 8:45 am]

BILLING CODE 6712–01–P

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## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

## Radio Broadcasting Services; Various Locations

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission, on its own motion, editorially amends the Table of FM Allotments to specify the actual classes of channels allotted to various communities. The changes in channel classifications have been authorized in response to applications filed by licensees and permittees operating on these channels. This action is taken pursuant to *Revision of Section 73.3573(a)(1) of the Commission's Rules Concerning the Lower Classification of an FM Allotment*, 4 FCC Rcd 2413 (1989), and the *Amendment of the Commission's Rules to permit FM Channel and Class Modifications [Upgrades] by Applications*, 8 FCC Rcd 4735 (1993).

**EFFECTIVE DATE:** October 28, 1997.

**FOR FURTHER INFORMATION CONTACT:** Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Report and Order, adopted October 8, 1997, and released October 17, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., 1231 20th Street, NW., Washington, DC. 20036, (202) 857–3800, facsimile (202) 857–3805.

**List of Subjects in 47 CFR Part 73**

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

## PART 73—[AMENDED]

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

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

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Arizona, is amended by removing Channel 246A and adding Channel 246C3 at Green Valley.

3. Section 73.202(b), the Table of FM Allotments under California, is amended by removing Channel 221B1 and adding Channel 221B at Clovis.

4. Section 73.202(b), the Table of FM Allotments under Colorado, is amended by removing Channel 245A and adding Channel 245C2 at Steamboat Springs.

5. Section 73.202(b), the Table of FM Allotments under Delaware, is amended by removing Channel 252A and adding Channel 253A at Seaford.

6. Section 73.202(b), the Table of FM Allotments under Mississippi, is amended by removing Channel 236A and adding Channel 236C3 at Winona.

7. Section 73.202(b), the Table of FM Allotments under Nebraska, is amended by removing Channel 285C3 and adding Channel 285C2 at York.

8. Section 73.202(b), the Table of FM Allotments under Nevada, is amended by removing Channel 256C3 and adding Channel 256A at Gardnerville-Minden.

9. Section 73.202(b), the Table of FM Allotments under Texas, is amended by removing Channel 292C2 and adding Channel 292C3 at Gonzales.

10. Section 73.202(b), the Table of FM Allotments under Washington, is amended by removing Channel 230C2 and adding Channel 230C3 at Ephrata.

Federal Communications Commission.

**John A. Karousos,**

*Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 97–28358 Filed 10–27–97; 8:45 am]

BILLING CODE 6712–01–F

# Proposed Rules

Federal Register
Vol. 62, No. 208
Tuesday, October 28, 1997

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

## DEPARTMENT OF THE TREASURY

### Customs Service

### 19 CFR Part 192

**RIN 1515–AC19**

## Exportation of Used Motor Vehicles

**AGENCY:** U.S. Customs Service, Department of the Treasury.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This document proposes amendments to the Customs Regulations which relate to the exportation of used self-propelled vehicles. These amendments are being proposed to clarify the intent of the regulations and provide for uniformity and standardized procedures. They are also being proposed to conform the regulations to legislation which was enacted since the regulations were originally written. The overall objective of the proposed amendments is to more efficiently and effectively deter the export of stolen vehicles.

**DATES:** Comments must be received on or before December 29, 1997.

**ADDRESSES:** Comments (preferably in triplicate) may be submitted to Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, N.W., 3rd Floor, Washington, D.C. 20229, and may be inspected at the same location.

**FOR FURTHER INFORMATION CONTACT:** Hugh Austin, Outbound Process, Office of Field Operations, 202–927–3735.

**SUPPLEMENTARY INFORMATION:**

### Background

Part 192 of the Customs Regulations (19 CFR Part 192) was established by the publication of T.D. 89–46 on April 18, 1989. These regulations implemented a provision of the Trade and Tariff Act of 1984 (19 U.S.C. 1627a) concerning the unlawful exportation of used self-propelled vehicles. Generally, that statute provides for civil penalties for the knowing importation or exportation, or attempted importation or exportation, of stolen self-propelled vehicles or equipment or any similar activity with respect to any self-propelled vehicle or part of such vehicle from which the vehicle identification number (VIN) has been removed, obliterated, tampered with or altered. The statute also directs that regulations be prescribed by the Secretary of the Treasury with regard to the procedures for the lawful exportation of used self-propelled vehicles. In implementing the existing regulations, both Customs and the public have encountered several difficulties which this proposed amendment to the regulations is intended to resolve.

### Proposed Amendments

The first proposed amendment to the existing regulations is to require the presentation to Customs of the original or certified copy of a title as proof of ownership of the vehicle to be exported. This is intended to eliminate a situation where there is a conflict between differences over a certified and a notarized copy of a title and the validity of each type of document. Certified copies can only be obtained from official issuing authorities. While the current regulations do not specifically address notarized copies, the proposed amendments explicitly disallow the use of notarized copies as proof of ownership. Customs field offices are currently accepting a variety of paperwork to establish ownership of vehicles presented for export. There is no national standard. Because all 50 states now have title laws, requiring the presentation of a title to show ownership will provide the field with a standard. By requiring that the documents be certified by the issuing authority, and not merely notarized, Customs will have a greater assurance of the authenticity of the documentation.

In instances when a vehicle owned by a foreign national and registered in a foreign country is being exported, where no title is available, Customs will require production of satisfactory proof of ownership by the exporter.

Realizing that there are instances where a party purchases a ''new'' car from a dealer and then immediately exports it without registering it in any state, and thus never receives a title in a state, Customs is making a provision for that situation by adding a document known as a ''manufacturer's statement of origin'' to the list of items which Customs will accept as proof of ownership. In those instances where a vehicle's purchaser does not intend to operate the vehicle in the U.S., Customs does not want to unnecessarily burden him by requiring that he obtain a state title. The manufacturer's statement of origin can provide a clear chain of possession from the manufacturer through the dealership to the present owner/exporter.

### Leased and Liened Vehicles

Today, there are many vehicles being operated legally in the United States by people who do not have title to the vehicle. Since the original regulations in this area were issued, there has been a significant increase in the number of vehicles which are ''on the road'' by virtue of a lease rather than a sale. In instances where a vehicle has been leased to an operator, the title to the vehicle is never intended to pass to the operator, because the right to use the vehicle will revert to the owner upon termination of the lease. Another instance of legal operation of a vehicle by one not in possession of a title occurs when a vehicle is purchased on time. Most often, in that situation, title is retained by the finance company until the note is paid, at which time the title will be transferred to the owner/operator. In recent years, Customs has seen an increase in the frequency in which either leased or liened vehicles are attempted to be exported without the knowledge or authorization of the actual title holder—the owner or the lien-holder. If the potential exporter keeps either the lease or note payments current until after the vehicle is exported, a check to see whether the vehicle is stolen at the time of export will not reveal anything suspicious. This is because, at the time of exportation, the vehicle is not yet stolen. Once the vehicle has been taken out of the reach of the lienholder or owner, payments are stopped and the theft takes place. In order to prevent this from happening as easily as it does now, Customs is proposing to amend the regulations to require that a party attempting to export a vehicle that is either leased or is subject to a lien present a letter from the lienholder or owner stating that they have knowledge

of and authorize the exportation of the vehicle.

**Other Areas of Clarification**

There are certain other areas where the current regulations have caused some uncertainty among groups or individuals, which this document proposes to clarify. In § 192.2(b) of the current regulations, the phrase ''in other cases'' appears at the beginning of the second sentence. Customs proposes to change the phrase to read ''in cases other than automobiles, trucks, vans, minivans, motorcycles, and buses''. This proposal is being made because some situations have developed where exporters and Customs field locations have interpreted the current phrase ''in other cases'' to mean situations in which individuals may present other types of documentation to prove ownership.

It is further proposed to amend § 192.2(b) by changing the word ''available'' to ''required'' in the phrase ''or other document if a certificate of title is not available as a result of a state regulatory requirement''. This change is being made to mandate presentation of titles at exportation if titles are required in the state in which the vehicle was purchased. All states require titles. However, some states only require titles for vehicles if they are of a certain age. Older vehicles, depending on the state, may or may not require titles. If the state does not require a title, then acceptable documentation for Customs export purposes would include a bill of sale.

Because of their growing popularity, and to prevent any misunderstanding about the intended coverage of the scope of vehicles intended to be covered by the regulation, the proposed regulation expressly includes vans and minivans as types of vehicles intended to be covered by the regulation.

**Time and Place of Presentation**

In an attempt to resolve some uncertainty which has arisen in the implementation of § 192.2(c) of the current regulations, which deals with the time when the required documentation must be presented, Customs is proposing the following amendments.

The current regulation states that the documentation must be presented at least 3 days prior to the lading or exportation of the vehicle. Questions have arisen whether that phrase meant calendar or business days. Those questions were made moot, however, by enactment of the Anti Car Theft Act of 1992. That Act amended the Tariff Act of 1930 by adding a new section, 19 U.S.C. 1646c, which requires that all persons or entities exporting used automobiles provide to Customs both the vehicle identification numbers and proof of ownership at least 72 hours before the export. In order to conform the regulatory requirements to the law and still provide port personnel the opportunity to examine vehicles which are being exported, it is proposed that the time for required presentation of documents in § 192.2(c) be changed to at least 72 hours, to include not less than 2 full business days for air or sea exports. The addition of the phrase ''at the port of exit'' is also being proposed as the place where documentation must be presented. There have been instances where documentation has been presented at a port which is not the exit port. The addition of this phrase is intended to remove any opportunity for confusion as to where the documentation is to be produced.

Because many vehicles are exported through land border ports, Customs is proposing to permit exporters to transmit copies of the required documentation by facsimile to the port of exit. This means that an exporter will not have to wait at the border for 72 hours after presenting the documentation. However, the original documents required will need to be presented, along with the vehicle, on the date of exit.

The proposed amendments change the terminology used in reference to the type of non-original documents which Customs will accept from ''facsimile'' to ''copy.'' This change is being made to avoid confusion resulting from current usage of the word ''facsimile''; the word is used often interchangeably with ''FAX.'' By using the word ''copy,'' Customs wishes to clarify that it intends to accept photocopies as well as ''faxes.'' In order that the regulations will be consistent, it is proposed to amend paragraph (d) by replacing the word ''facsimile'' with the word ''copy''.

A new paragraph (e) is being proposed which states that each Port Director has the authority to establish a time and place for presentation of original documentation and inspection of vehicles. Customs believes that in order to implement the law, it is necessary to impose constraints on times when the original documentation and vehicles will be accepted. By giving the Port Director the authority to set times and places for acceptance of original documents, it is intended that processing of exported used vehicles will be more efficient for both Customs and exporters in this time of limited resources.

**Comments**

Before adopting this proposal, consideration will be given to any written comments (preferably in triplicate) that are timely submitted to Customs. All such comments received from the public pursuant to this notice of proposed rulemaking will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b), Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9:00 a.m. and 4:30 p.m., at the Regulations Branch, U.S. Customs Service, 1300 Pennsylvania Avenue, NW., 3rd Floor Washington, D.C.

**Regulatory Flexibility Act**

In so far as the proposed amendment is intended to assist Customs exercise its law enforcement responsibilities with a minimum burden on legitimate exporters of used vehicles, pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), it is certified that the amendment, if adopted, will not have a significant economic impact on a substantial number of small entities. Accordingly, it is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

**Executive Order 12866**

The proposed amendment does not meet the criteria for a ''significant regulatory action'' under E.O. 12866.

**Paperwork Reduction Act**

The collection of information contained in this rulemaking has been submitted to the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995. (44 U.S.C. 3507).

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless the collection of information displays a valid control number.

The clarification of the collection of information in these regulations is in § 192.2. All information required by this proposed amendment is contained or identified in the above-cited section. This information is to be maintained and provided in the form of documents which are necessary to ensure that the Customs Service will be able to effectively administer the laws it is charged with enforcing while, at the same time, imposing a minimum burden on the public it is serving. Respondents or recordkeepers are already required by state statute or regulation to maintain or have most of the information covered in

this proposed regulation. The likely respondents or recordkeepers are business organizations and individuals, including exporters.

*Estimated total annual reporting and/or recordkeeping burden:* 83,330 hours.

*Estimated average annual burden per respondent/recordkeeper:* 10 minutes.

*Estimated number of respondents and/or recordkeepers:* 500,000.

*Estimated annual frequency of responses:* 1.

Comments concerning the collections of information should be sent to the Office of Management and Budget, Attention: Desk Officer of the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, D.C. 20503. A copy should also be sent to the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, N.W., Washington, D.C. 20229. Comments should be submitted within the time frame that comments are due regarding the substance of the proposal.

Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or startup costs and costs of operations, maintenance, and purchase of services to provide information.

## Drafting Information

The principal author of this document was Peter T. Lynch, Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

## List of Subjects in 19 CFR Part 192

Customs duties and inspection, Exports, Motor vehicles, Penalties.

## Proposed Amendments

It is proposed to amend Part 192, Customs Regulations (19 CFR Part 192), as set forth below:

## PART 192—EXPORT CONTROL

1. The authority citation for Part 192, Customs Regulations (19 CFR Part 192), is proposed to be revised to read as follows:

**Authority:** 19 U.S.C. 66, 1624, 1627a, 1646a, 1646c.

2. It is proposed to amend § 192.2 by revising paragraphs (b), (c) and (d) and adding a new paragraph (e) to read as follows:

### § 192.2 Requirements for exportation.

* * * * *

(b) *Documentation required.* (1) *For certain registered vehicles owned by the exporter.* In the case of automobiles, trucks, vans, minivans, motorcycles and buses owned by the exporter and registered in any state of the United States, the following documentation is required to be presented at the port of exit:

(i) An original or certified copy of the Certificate of Title from a state issuing authority. A notarized copy of the Certificate of Title is not acceptable; and

(ii) Two copies of the original or certified copy of the Certificate of Title.

(2) *For certain vehicles purchased with the intention of exportation.* In the case of automobiles, trucks, vans, minivans, motorcycles and buses purchased from a dealer and not registered in any state of the United States because of plans to immediately export, an original manufacturer's statement of origin and two copies of the manufacturer's statement of origin are required to be presented at the port of exit.

(3) *For certain vehicles where a Certificate of Title is not required as a result of state or foreign country requirements.* In the case of automobiles, trucks, vans, minivans, motorcycles and buses owned by a foreign national and registered in a foreign country or instances in which a state does not require a Certificate of Title, an original document that provides satisfactory proof of ownership by the exporter and two copies of that document are required to be presented at the port of exit.

(4) *For certain leased or liened vehicles.* In the case of automobiles, trucks, vans, minivans, motorcycles and buses that are leased or on which there is a lien, a letter from the lienholder or, if leased, the owner stating that the lienholder or owner agrees that the vehicle may be exported is required to be presented at the port of exit. The letter must include the name, address and telephone number of the lienholder or owner and must include the Vehicle Identification Number of the vehicle.

(5) *For other self-propelled vehicles.* In the case of self-propelled motorized vehicles other than automobiles, trucks, vans, minivans, motorcycles, and buses, an original or certified Certificate of Title, memorandum of ownership, or right of possession, or any other document sufficient to prove lawful ownership, such as an original bill of sale or an original sales invoice, as well as 2 copies of the document, shall be presented.

(c) *When presented.* (1) *Exportation by vessel or aircraft.* If the vehicle is to be transported by vessel or aircraft, all documentation and the vehicle must be presented to Customs at the port of exit at least 72 hours, to include not less than 2 full business days, prior to lading in accordance with such directives as may be issued by the Port Director pursuant to paragraph (e) of this part.

(2) *Exportation at land border port.* If the vehicle is to be transported by rail, highway, or under its own power, copies of the required documentation may be sent or transmitted to the port of exit in a manner so that they will arrive at least 72 hours prior to the intended time of exportation. The original documents need to be presented at time of exit along with the vehicle. The vehicle and original documentation shall be presented at the port of exportation in accordance with such directives as may be issued by the Port Director pursuant to paragraph (e) of this part.

(d) *Authentication of documentation.* Customs shall authenticate both copies of the documents submitted, one of which shall remain in the possession of the exporter and one of which shall be collected by Customs. Authentication will include the stamping of the copies of the documents with the date and time of presentation of the documents. The authenticated copy of the document will be the only acceptable evidence from the exporter of compliance with the requirements of this section.

(e) *Time and place of document presentation.* Each Port Director shall establish and publicize the hours and location at which original documentation required by this section will be received and the hours and place for presentation of the vehicle.

**George J. Weise,**

*Commissioner of Customs.*

Approved: September 24, 1997.

**John P. Simpson,**

*Deputy Assistant Secretary of the Treasury.*

[FR Doc. 97–28490 Filed 10–27–97; 8:45 am]

BILLING CODE 4820–02–P

## DEPARTMENT OF THE INTERIOR

## Bureau of Indian Affairs

## 25 CFR Part 248

**RIN 1076–AD86**

## Use of Columbia River Indian In-Lieu Fishing Sites

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Proposed rule with request for comments.

**SUMMARY:** The Bureau of Indian Affairs (BIA) is writing into plain English the existing regulations governing the use of Columbia River Indian In-Lieu Fishing Sites. We are doing this as part of the President's regulatory reinvention initiative.

**DATES:** Comments must be submitted on or before December 29, 1997.

**ADDRESSES:** Submit comments on this rule to: Chuck James, Area Archeologist, Portland Area Office, Bureau of Indian Affairs, 911 NE. 11 Ave., Portland, OR 97232, (503) 231–6229.

**FOR FURTHER INFORMATION CONTACT:** Chuck James (Area Archeologist), (503) 231–6229.

**SUPPLEMENTARY INFORMATION:** The purpose of this rulemaking is to revise the regulations governing the use of Columbia River Indian In-Lieu Fishing Sites. We have written these regulations in plain English to make them easier for users to read and understand.

### Executive Order 12988

The Department has certified to the Office of Management and Budget (OMB) that these proposed regulations meet the applicable standards provided in sections 3(a) and 3(b)(2) of Executive Order 12988.

### Executive Order 12866

This proposed rule is not a significant regulatory action and does not require Office of Management and Budget review under Executive Order 12866.

### Regulatory Flexibility Act

This rule 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.*).

### Executive Order 12630

The Department has determined that this rule does not have significant ''takings'' implications. The rule does not pertain to ''taking'' of private property interests, nor does it impact private property.

### Executive Order 12612

The Department has determined that this rule does not have significant Federalism effects because it pertains solely to Federal-tribal relations and will not interfere with the roles, rights, and responsibilities of states.

### NEPA Statement

The Department has determined that this rule does not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement is required under the National Environmental Policy Act of 1969.

### Paperwork Reduction Act of 1995

This rule does not contain any collection of information requiring approval under the Paperwork Reduction Act of 1995.

### Unfunded Mandates Reform Act of 1995

This rule imposes no unfunded mandates on any governmental or private entity and is in compliance with the provisions of the Unfunded Mandates Reform Act of 1995.

### Drafting Information

The primary author of this document is Chuck James, Area Archaeologist, Bureau of Indian Affairs, Department of the Interior.

### List of Subjects in 25 CFR Part 248

Fisheries, Fishing, Indians, Indians—claims, Indians—law.

For the reasons set out in the preamble, Bureau of Indian Affairs proposes to revise part 248 as follows:

## PART 248—USE OF COLUMBIA RIVER INDIAN IN-LIEU FISHING SITES

Sec.

248.1 What definitions apply to this part?
248.2 What lands are subject to these regulations in this part?
248.3 Who is eligible to use Columbia River in-lieu fishing sites?
248.4 How may I use the sites?
248.5 What identification do I need in order to use a site?
248.6 What requirements must I obey in order to be able to use a site?
248.7 How does this part affect tribal treaty rights?
248.8 What will happen if I damage government-owned property?
248.9 Can I build a structure on a site?
248.10 What sanitation requirements must I meet?
248.11 What am I responsible for if I use the facilities?
248.12 What will happen if I abandon property?
248.13 What other restrictions apply to use of the sites?
248.14 Will I have to pay to use a site?
248.15 Can I appeal an administrative action?

**Authority:** 5 U.S.C. 301; 25 U.S.C. 2, 9.

### § 248.1 What definitions apply to this part?

*Abandoned property* means property left at a site while the owner of the property is not actively engaged in fishing or drying or processing fish. Abandoned property may include:

(1) Vehicles;
(2) Mobile trailers;
(3) Campers;
(4) Tents;
(5) Tepees;
(6) Boats; or
(7) Other personal property.

*Area Director* means the position responsible for administration of the Portland Area of the Bureau of Indian Affairs.

*Campfire* means fire, not within any building, motor home or trailer, that is used for cooking, personal warmth, lighting, ceremonial or aesthetic purposes.

*Damage* means to injure, mutilate, deface, destroy, cut, chop, girdle, dig, excavate, kill, or in any way harm or disturb.

*In-lieu fishing sites* means any lands acquired by the Secretary of War and transferred to the Secretary of the Interior pursuant to the Act of March 2, 1945 (59 Stat. 22) as amended to replace Indian fishing grounds submerged or destroyed as a result of the construction of the Bonneville Dam.

*Secretary* means the Secretary of the Interior or his/her designee.

*Site* means an in-lieu fishing site as defined in this section.

*Vehicle* means any device in, upon, or by which any person or property is or may be transported, and including any motor, frame, chassis, or body of any motor vehicle, or camper shell, except devices used exclusively upon stationary rails or tracks.

### § 248.2 What lands are subject to the regulations in this part?

This part applies to in-lieu fishing sites as defined in § 248.1.

### § 248.3 Who is eligible to use Columbia River in-lieu fishing sites?

Members of the general public may not use Columbia River in-lieu fishing sites. You may use a site only if:

(a) You are a member of any of the following tribes:

(1) Yakama;
(2) Umatilla;
(3) Warms Springs; or
(4) Any other tribe that had treaty fishing rights that were inundated or destroyed by the Bonneville Dam; and

(b) You comply with the requirements of this part and of any additional guidance that the Area Director may issue to implement this part.

**§ 248.4 How may I use the sites?**

If you meet the criteria in § 248.3, you may use a site:

(a) For access to usual and accustomed fishing areas and ancillary facilities; and

(b) For camping with your family (while you are fishing?).

**§ 248.5 What identification do I need in order to use a site?**

(a) When you use a site you must have with you either:

(1) Your tribal identification card; or

(2) If you belong to a tribe specified in § 248.3(a)(4), a special identification issued by the Area Director.

(b) You must show the identification required in paragraph (a) of this section to any authorized Federal, State, or local official who asks to see it.

**§ 248.6 What requirements must I obey in order to be able to use a site?**

(a) You may use a site only if you obey:

(1) The requirements of tribal, State, and Federal laws and regulations (unless they conflict with your treaty tribe's rights); and

(2) Any additional requirements that the Area Director may develop to implement this part.

(b) The Area Director may suspend or withdraw your access and use privileges if you do not follow the requirements of this section.

**§ 248.7 How does this part affect tribal treaty rights?**

(a) This part does not limit or affect the treaty rights of any tribe.

(b) You are not required to obey State fishing laws or regulations if:

(1) You are an Indian properly exercising tribal treaty rights; and

(2) The State laws or regulations are not compatible with your treaty rights.

**§ 248.8 What will happen if I damage government-owned property?**

If you commit any act of vandalism, depredation, destruction, theft, or misuse of land, buildings, fences, signs, or other structures that are the property of the United States, you can be prosecuted under applicable Federal or State law.

**§ 248.9 Can I build a structure on a site?**

You may erect, place, or maintain dwellings, camping facilities, and other structures (such as fish drying facilities and fish platforms) if you need them for treaty fishing or related activities.

**§ 248.10 What sanitation requirements must I meet?**

(a) You must use the sites in conformance with the health, sanitation, and safety requirements of State or local law. If there are no appropriate State or local laws, you must follow the health, sanitation, and safety requirements of the U.S. Public Health Service.

(b) The Area Director may suspend or withdraw your access and use privileges if:

(1) You violate the requirements referred to in paragraph (a) of this section; and

(2) You repeat the violation after having been given a notice to cease and desist.

**§ 248.11 What am I responsible for if I use the facilities?**

(a) You are responsible for:

(1) Campsites, drying sheds and other facilities during the time you occupy or use them; and

(2) Any personal property that you erect, place, or maintain on the site during the time you occupy the site, including:

(i) Tents;

(ii) Tepees;

(iii) Campers;

(iv) Mobile trailers;

(v) Temporary drying sheds; and

(vi) Fishing platforms.

(b) Neither the United States nor any of its employees is responsible for the safety or condition of any personal property.

**§ 248.12 What will happen if I abandon property?**

If you abandon property at a site, it may be removed without your consent and disposed of at your expense, if the Area Director approves.

**§ 248.13 What other restrictions apply to use of the sites?**

The Area Director may prescribe and post at the sites regulations covering:

(a) Camping;

(b) Picnicking;

(c) Use of alcoholic beverages;

(d) Setting or use of fires;

(e) Use of the sites for cleaning fish;

(f) Deposit of garbage, paper, cans, bottles, or rubbish of any kind; or

(g) Use of the sites for any commercial activity (including commercial purchase of fish).

**§ 248.14 Will I have to pay to use a site?**

No. Neither you nor any member of your family will be charged for using a site in accordance with this part.

**§ 248.15 Can I appeal an administrative action?**

You may appeal any decision made by the Area Director under this part to the Commissioner of Indian Affairs. You may appeal any decision of the Commissioner of Indian Affairs to the Secretary of the Interior in accordance with part 2 of this chapter.

Dated: October 17, 1997.

**Ada E. Deer,**

*Assistant Secretary—Indian Affairs.*

[FR Doc. 97–28493 Filed 10–27–97; 8:45 am]

BILLING CODE 4310–02–P

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## DEPARTMENT OF THE TREASURY

## Internal Revenue Service

## 26 CFR Parts 1 and 301

**[REG–105162–97]**

**RIN–1545–AV16**

## Treatment of Changes in Elective Entity Classification

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking and notice of public hearing.

**SUMMARY:** This document contains proposed regulations addressing elective changes in entity classification. The proposed regulations describe how elective changes in classification will be treated for federal tax purposes. The proposed regulations would affect business entities and their members. This document also contains a notice of public hearing on these proposed regulations.

**DATES:** Written comments must be received by January 26, 1998. Requests to speak (with outlines of oral comments) at the public hearing scheduled for February 24, 1997, must be submitted by January 26, 1998.

**ADDRESSES:** Send submissions to: CC:DOM:CORP:R (REG–105162–97), room 5228, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. In the alternative, submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:R (REG–105162–97), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the ''Tax Regs'' option of the IRS Home Page, or by submitting comments directly to the IRS Internet site at: http://www.irs.ustreas.gov/prod/tax—regs/comments.html. The public hearing will be held in room 2615, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Concerning the regulations, Jeff Erickson, (202) 622–3070 (not a toll-free number); concerning international issues, Philip Tretiak or Ronald M. Gootzeit, (202) 622–3860 (not a toll free number); concerning submissions and the hearing, Evangelista Lee, (202) 622–7190 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

## Background

This document proposes to amend the current Income Tax Regulations (26 CFR Parts 1 and 301) relating to the classification of entities for federal tax purposes. On December 18, 1996, the IRS and Treasury published final regulations under section 7701 (final regulations), replacing the former classification rules with an elective regime. See TD 8697 (1997–2 I.R.B. 11).

Under the final regulations, a business entity that is not specifically classified as a corporation in the final regulations (an eligible entity) can elect its classification for federal tax purposes under certain circumstances. An eligible entity with at least two members can elect to be classified as a partnership or as an association taxable as a corporation. An eligible entity with a single member can elect to be classified as an association or as an entity that is disregarded as an entity separate from its owner. An eligible entity may also elect to change its classification, except that an election may not be made more than once in any sixty month period. An eligible entity that does not make an election is classified under certain default provisions.

## Explanation of Provisions

### *Characterization of Elective Changes in Classification*

The proposed regulations describe how elective changes in an entity's classification will be treated for federal tax purposes. Under the final regulations, there are four possible changes in classification by election: (i) a partnership elects to be an association; (ii) an association elects to be a partnership; (iii) an association elects to be a disregarded entity; and (iv) a disregarded entity elects to be an association. There are two other possible ways in which an entity's classification could change (a partnership converts to a disregarded entity or a disregarded entity converts to a partnership) but these changes occur only as a result of a change in the number of members, not as the result of an elective change.

The proposed regulations do not address the form of these two possible types of changes.

The proposed regulations provide a specific characterization for each of the four possible elective changes. In each case, the characterization provided in the proposed regulations attempts to minimize the tax consequences of the change in classification and achieve administrative simplicity. The proposed regulations provide that if an association elects to be classified as a partnership, the association is deemed to liquidate by distributing its assets and liabilities to its shareholders. Then, the shareholders are deemed to contribute all of the distributed assets and liabilities to the partnership. This characterization of an elective change from an association to a partnership is consistent with Rev. Rul. 63–107 (1963–1 C.B. 71).

If a partnership elects to be classified as an association, the partnership is deemed to contribute all of its assets and liabilities to the association in exchange for stock in the association. Then, the partnership is deemed to liquidate by distributing stock in the association to its partners. The proposed regulations do not affect the holdings in Rev. Rul. 84–111 (1984–2 C.B. 88), in which the IRS ruled that it would respect the particular form undertaken by the taxpayers when a partnership converts to a corporation.

If an association elects to be disregarded as an entity separate from its owner, the association is deemed to liquidate by distributing its assets and liabilities to its sole owner. Conversely, if an eligible entity that is disregarded as an entity separate from its owner elects to be classified as an association, the owner of the eligible entity is deemed to contribute all of the assets and liabilities of that entity to the association in exchange for stock of the association.

The proposed regulations also provide that the tax treatment of an elective change in classification is determined under all relevant provisions of the Internal Revenue Code and general principles of tax law, including the step transaction doctrine. This provision in the proposed regulations is intended to ensure that the tax consequences of an elective change will be identical to the consequences that would have occurred if the taxpayer had actually taken the steps described in the proposed regulations. The IRS and Treasury request comments on the application of general principles of tax law to the transactions that are deemed to occur on an elective change in classification.

### *Change in Number of Members of Entity*

The proposed regulations address the effect of a change in the number of members on the classification of an entity. Under the proposed regulations, if there is a change in the number of members of an association, the classification of the entity is not affected. If an eligible entity classified as a partnership subsequently has only one member (and is still treated as an entity under local law), the entity will be disregarded as an entity separate from its owner. If a single member entity that is disregarded as an entity separate from its owner subsequently has more than one member, the entity is classified as a partnership as of the date the entity has more than one member. The classifications provided in the proposed regulations can be changed by election, assuming that the entity is not subject to the sixty month limitation on elections.

### *Timing of Elective Changes in Classification*

The proposed regulations provide that an election to change the classification of an entity is treated as occurring at the start of the day for which the election is effective. Any transactions that are deemed to occur as a result of the change in classification are treated as occurring immediately before the close of the day before the effective date of the election. For example, if an election is made to convert from an association to a partnership effective on January 1, the entity is treated as a partnership on January 1, and the deemed transactions specified in the proposed regulations are treated as occurring immediately before the close of December 31. As a result, the last day of the association s taxable year will be December 31 and the first day of the partnership's taxable year will be January 1.

### *Treatment of Foreign Eligible Entities*

Any eligible entity, including a foreign eligible entity whose classification is not relevant for federal tax purposes, may elect to change its classification. The IRS and Treasury request comments on the appropriateness of allowing such a foreign eligible entity to make a classification election, and comments on what the federal tax consequences of such an election should be (e.g., with respect to the basis of property held by the entity).

### *Foreign Per Se Entities*

The final regulations provide a list of the names of certain foreign business entities that are treated as corporations for federal tax purposes. In most cases,

the name by which an entity will be known is provided by the statutory corporate law of the relevant jurisdiction. In certain cases, however, the corporate law does not provide a statutory name. In these jurisdictions, taxpayers and practitioners often fill the statutory void with a name derived from a number of the statutory characteristics of the entity. In an effort to make the list of foreign per se corporations more accessible, the final regulations use the commonly used non-statutory term in certain cases where the statute does not provide a defined name. To minimize any uncertainty, however, the provisions of § 301.7701–2(b)(8) (iii) and (iv) were included in the final regulations to address this issue. In response to comments from taxpayers, these subsections of the final regulations are clarified to provide guidance on the terms used in the final regulations. Furthermore, the regulations clarify that the term Berhad used with regard to Malaysia does not include *a Sendirian Berhad* (the equivalent of a private limited company). The regulations also clarify that, in relation to Mexico, the term Sociedad Anonima includes a Sociedad Anonima that chooses to apply the variable capital provision of Mexican corporate law (Sociedad Anonima de Capital Variable). The fact that capital may be varied does not make this a different type of entity from a Sociedad Anonima that does not choose to apply the variable capital provision. These clarifications are not intended to change the interpretation of the final regulations.

The proposed regulations also clarify the treatment of the Finnish, Maltese, and Norwegian entities specified in the final regulations. Effective January 1, 1996, Maltese and Norwegian corporate law recognized a distinction between public and private companies, and the proposed regulations reflect this change. The proposed regulations also provide that the rules of the final regulations with regard to the Maltese and Norwegian entities may be applied (when these proposed regulations are finalized) as though the entities specified in the proposed regulations had been included in the final regulations issued on December 18, 1996. Thus, a Maltese or Norwegian entity that is no longer treated as a per se corporation under the regulations would be able to make an election within 75 days of the date these proposed regulations are finalized, and such election could be effective as of January 1, 1997. Finnish law, since September 1, 1997, has recognized a similar distinction between public and private companies. It is proposed that a Finnish entity that is no longer treated as a per se corporation under the regulations would be able to make an election within 75 days of the date these proposed regulations are finalized, and such election could be effective as of September 1, 1997.

*Special Basis Adjustments Under Section 743*

Section 743 provides that the basis of partnership property is not adjusted as the result of a transfer of an interest in the partnership by sale or exchange unless the partnership has made an election under section 754. If a section 754 election is made, the transferee partner is treated as having a special basis adjustment with respect to partnership property. This adjustment constitutes an adjustment to the basis of partnership property with respect to the transferee partner only. Some uncertainty has remained as to the treatment of this special basis adjustment upon the contribution of the partnership property to a corporation in a section 351 exchange, and because the proposed regulations provide for a deemed contribution by the partnership to a corporation in an elective conversion to an association, the proposed regulations address this uncertainty.

The proposed regulations provide that a corporate transferee's basis in property transferred by a partnership in a transfer described in section 351 includes any special basis adjustment under section 743. The special basis adjustment is also taken into account in determining the partner's basis in the stock received in the exchange. For example, assume a partnership owns Property X, which has a common basis of $100 for the partnership and in which Partner A has a $5 special basis adjustment under section 743(b). Subsequently, the partnership validly elects to be classified as an association. The partnership is deemed to contribute all of its assets and liabilities to the association in exchange for stock in the association, and immediately thereafter, the partnership liquidates by distributing the stock of the association to its partners. If the transfer of the assets to the association would be a transfer described in section 351, then under the proposed regulations, the association's basis in Property X includes Partner A's $5 special basis adjustment. Thus, the association has a $105 basis in Property X (Partner A's $5 special basis adjustment plus the partnership's $100 common basis). Partner A's basis in the association's stock will reflect the $5 special basis adjustment previously on Property X.

The proposed regulations also provide, however, that the amount of gain, if any, recognized by the partnership on the transfer is determined without reference to any special basis adjustment. The partner with the special basis adjustment can then use the special basis adjustment to reduce its share of any gain recognized by the partnership. This approach of determining gain at the partnership level and allowing the partner to use the special basis adjustment as an offset is similar to the treatment of a sale of property with a special basis adjustment.

**Proposed Effective Date**

Except as otherwise specified, these regulations are proposed to apply as of the date the final regulations are published in the **Federal Register**.

**Special Analyses**

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose on small entities a collection of information requirement, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

**Comments and Public Hearing**

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (preferably a signed original and eight (8) copies) that are submitted timely to the IRS. All comments will be available for public inspection and copying.

A public hearing has been scheduled for February 24, 1997, at 10 a.m., in room 2615, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC. Because of access restrictions, visitors will not be admitted beyond the Internal Revenue Building lobby more than 15 minutes before the hearing starts.

The rules of 26 CFR 601.601(a)(3) apply to the hearing.

Persons that wish to present oral comments at the hearing must submit timely written comments and an outline of the topics to be discussed and the time to be devoted to each topic by (preferably a signed original and eight (8) copies) January 26, 1998.

A period of 10 minutes will be allotted to each person for making comments.

An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

**Drafting Information**

The principal authors of these regulations are Ann M. Veninga, Office of Chief Counsel (Passthroughs and Special Industries) and Philip Tretiak, Office of Associate Chief Counsel (International). However, other personnel from the IRS and Treasury Department participated in their development.

**List of Subjects**

*26 CFR Part 1*

Income taxes, Reporting and recordkeeping requirements.

*26 CFR Part 301*

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

**Proposed Amendments to the Regulations**

Accordingly, 26 CFR parts 1 and 301 are proposed to be amended as follows.

## PART 1—INCOME TAXES

**Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

**Authority:** 26 U.S.C. 7805 * * *

**Par. 2.** Section 1.743–2 is added under the undesignated centerheading ''Transfer of Interests in a Partnership'' to read as follows:

### § 1.743–2 Transfer of property to a corporation.

(a) *Basis in transferred property.* A corporations adjusted tax basis in property transferred to the corporation by a partnership in a transfer described in section 351 is determined with reference to any special basis adjustment to the property under section 743(b) (other than any special basis adjustment that reduces a partner's gain under paragraph (b) of this section).

(b) *Partnership gain.* The amount of gain, if any, recognized by a partnership on a transfer of property by the partnership to a corporation in a transfer described in section 351 is determined without reference to any special basis adjustment to the transferred property under section 743(b). The amount of gain, if any, recognized by the partnership on the transfer that is allocated to a partner with a special basis adjustment in the transferred property is adjusted to reflect the partner's special basis adjustment in the transferred property.

(c) *Basis in stock.* The partnership's adjusted tax basis in stock received from a corporation in a transfer described in section 351 is determined without reference to the special basis adjustment in property transferred to the corporation in the section 351 exchange. A partner with a special basis adjustment in property transferred to the corporation, however, has a special basis adjustment in the stock received by the partnership in the section 351 exchange in an amount equal to the partner's special basis adjustment in the transferred property, reduced by any special basis adjustment that reduced the partner's gain under paragraph (b) of this section.

(d) *Effective date.* This section applies to transfers that occur on or after the date final regulations are published in the **Federal Register**.

## PART 301—PROCEDURE AND ADMINISTRATION

**Par. 3.** The authority citation for part 301 continues to read in part as follows:

**Authority:** 26 U.S.C. 7805 * * *

**Par. 4.** Section 301.6109–1 is amended as follows:

1. Paragraph (d)(2)(ii) is removed and reserved.

2. Paragraph (h) is redesignated as paragraph (i) and the first sentence of newly designated paragraph (i)(1) is amended by removing the language ''paragraph (h)'' and adding ''paragraph (i)'' in its place.

3. A new paragraph (h) is added.

The addition reads as follows:

### § 301.6109–1 Identifying numbers.

* * * * *

(h) *Special rules for certain entities under § 301.7701–3*—(1) *General rule.* Any entity that has an employer identification number (EIN) will retain that EIN if its federal tax classification changes under § 301.7701–3.

(2) *Special rules for entities that are disregarded as entities separate from their owners*—(i) *When an entity becomes disregarded as an entity separate from its owner.* Except as otherwise provided in regulations or other guidance, a single owner entity that is disregarded as an entity separate from its owner under § 301.7701–3, must use its owner's taxpayer identifying number (TIN) for federal tax purposes.

(ii) *When an entity that was disregarded as an entity separate from its owner becomes recognized as a separate entity.* If a single owner entity's classification changes so that it is recognized as a separate entity for federal tax purposes, and that entity had an EIN, then the entity must use that EIN and not the TIN of the single owner. If the entity did not already have its own EIN, then the entity must acquire an EIN and not use the TIN of the single owner.

(3) *Effective date.* This paragraph (h) applies to changes in classification that occur on or after the date on which these regulations are published as final regulations in the **Federal Register.**

**Par. 5.** Section 301.7701–2 is amended as follows:

1. Paragraph (b)(8)(i) is amended by revising the entries for Finland, Malta, and Norway.

2. Paragraph (b)(8)(ii)(A) is redesignated as paragraph (b)(8)(ii)(A)(*1*) and the language ''and'' at the end of the paragraph is removed.

3. Paragraph (b)(8)(ii)(B) is redesignated as paragraph (b)(8)(ii)(A)(*2*) and the period at the end of the paragraph is removed and the language ''; and '' is added in its place.

4. Paragraph (b)(8)(ii) heading and introductory text are redesignated as paragraph (b)(8)(ii)(A) heading and introductory text, and a new paragraph heading is added for paragraph (b)(8)(ii).

5. Paragraphs (b)(8)(ii)(A)(*3*) and (b)(8)(ii)(B) are added.

6. Paragraphs (b)(8)(iii), (b)(8)(iv), and (e) are revised.

The revisions and additions read as follows:

### § 301.7701–2 Business entities; definitions.

* * * * *

(b) * * *

(8) * * *

(i) * * *

Finland, Julkinen Osakeyhtio/Publikt Aktiebolag

* * * * *

Malta, Public Limited Company

* * * * *

Norway, Allment Aksjeselskap

* * * * *

(ii) *Clarification of list of corporations in paragraph (b)(8)(i) of this section—(A) Exceptions in certain cases.* * * *

* * * * *

(*3*) With regard to Malaysia, a Sendirian Berhad.

(B) *Inclusions in certain cases*. With regard to Mexico, the term Sociedad Anonima includes a Sociedad Anonima that chooses to apply the variable capital provision of Mexican corporate law (Sociedad Anonima de Capital Variable).

(iii) *Public companies*. For purposes of paragraph (b)(8)(i) of this section, with regard to Cyprus, Hong Kong, Jamaica, and Trinidad and Tobago, the term Public Limited Company includes any Limited Company that is not defined as a private company under the corporate laws of those jurisdictions. In all other cases, where the term Public Limited Company is not defined, that term shall include any Limited Company defined as a public company under the corporate laws of the relevant jurisdiction.

(iv) *Limited companies*. For purposes of this paragraph (b)(8), any reference to a Limited Company includes, as the case may be, companies limited by shares and companies limited by guarantee.

* * * * *

(e) *Effective date*. Except as otherwise provided in this paragraph (e), the rules of this section apply as of January 1, 1997. The reference to the Finnish, Maltese, and Norwegian entities in paragraph (b)(8)(i) of this section is applicable on the date the final regulations are published in the Federal Register. Any Maltese or Norwegian entity that becomes an eligible entity as a result of paragraph (b)(8)(i) of this section in effect on the date final regulations are published in the **Federal Register** may elect (within 75 days of the date final regulations are published in the **Federal Register**) to be classified for federal tax purposes as an entity other than a corporation retroactive to any period from and including January 1, 1997. Any Finnish entity that becomes an eligible entity as a result of paragraph (b)(8)(i) of this section in effect on the date final regulations are published in the **Federal Register** may elect (within 75 days of the date final regulations are published in the **Federal Register**) to be classified for federal tax purposes as an entity other than a corporation retroactive to any period from and including September 1, 1997.

**Par. 6.** Section 301.7701–3 is amended as follows:

1. A sentence is added at the end of paragraph (c)(1)(iv).

2. Paragraph (c)(2)(iii) is added.

3. A heading is added to paragraph (d)(1).

4. Paragraph (f) is redesignated as paragraph (h) and newly designated paragraph (h)(1) is revised.

5. Paragraphs (f) and (g) are added.

The revision and additions read as follows:

**§ 301.7701–3 Classification of certain business entities.**

* * * * *

(c) * * *

(1) * * *

(iv) *Limitation*. * * * An election by a newly-formed eligible entity that is effective on the date of formation is not considered a change for purposes of this paragraph (c)(1)(iv).

* * * * *

(2) * * *

(iii) *Changes in classification*. For purposes of paragraph (c)(2)(i) of this section, if an election under paragraph (c)(1)(i) of this section is made to change the classification of an entity, each person who was an owner on the date that any transactions under paragraph (g) of this section are deemed to occur, and who is not an owner at the time the election is filed, must also sign the election. This paragraph (c)(2)(iii) applies to elections filed on or after the date final regulations are published in the **Federal Register**.

(d) *Special rules for foreign eligible entities*—(1) *Definition of relevance*. * * *

* * * * *

(f) *Changes in number of members of an entity*—(1) *Associations*. The classification of an eligible entity as an association is not affected by any change in the number of members of the entity.

(2) *Partnerships and single member entities*. An eligible entity classified as a partnership is disregarded as an entity separate from its owner as of the date the entity has only one member. A single member entity disregarded as an entity separate from its owner is classified as a partnership as of the date the entity has more than one member.

(3) *Effect on sixty month limitation*. A change in the number of members of an entity does not result in the creation of a new entity for purposes of the sixty month limitation on elections under paragraph (c)(1)(iv) of this section.

(4) *Examples*. The following examples illustrate the application of this paragraph (f):

*Example 1*. (i) On April 1, 1998, A and B, U.S. persons, form X, a foreign eligible entity. X is treated as an association under the default provisions of paragraph (b)(2)(i) of this section, and X does not make an election to be classified as a partnership. A subsequently purchases all of B's interest in X.

(ii) Under paragraph (f)(1) of this section, X continues to be classified as an association. X, however, can subsequently elect to be disregarded as an entity separate from A. The sixty month limitation of paragraph (c)(1)(iv) of this section does not prevent X from making an election because X has not made a prior election under paragraph (c)(1)(i) of this section.

*Example 2*. (i) On April 1, 1998, A and B, U.S. persons, form X, a foreign eligible entity. X is treated as an association under the default provisions of paragraph (b)(2)(i) of this section, and X does not make an election to be classified as a partnership. On January 1, 1999, X elects to be classified as a partnership effective on that date. Under the sixty month limitation of paragraph (c)(1)(iv) of this section, X cannot elect to be classified as an association until January 1, 2004 (i.e., sixty months after the effective date of the election to be classified as a partnership).

(ii) On June 1, 1999, A purchases all of B's interest in X. After A's purchase of B's interest, X can no longer be classified as a partnership because X has only one member. Under paragraph (f)(2) of this section, X is disregarded as a separate entity as of the date A becomes the only member of X. X, however, is not treated as a new entity for purposes of paragraph (c)(1)(iv) of this section. As a result, the sixty month limitation of paragraph (c)(1)(iv) of this section continues to apply to X and X cannot elect to be classified as an association until January 1, 2004 (i.e., sixty months after January 1, 1999, the effective date of the election by X to be classified as a partnership).

(5) *Effective date*. This paragraph (f) applies as of the date the final regulations are published in the **Federal Register**.

(g) *Elective changes in classification*—(1) *Deemed treatment of elective change*—(i) *Partnership to association*. If an eligible entity classified as a partnership elects under paragraph (c)(1)(i) of this section to be classified as an association, the following is deemed to occur: The partnership contributes all of its assets and liabilities to the association in exchange for stock in the association, and immediately thereafter, the partnership liquidates by distributing the stock of the association to its partners.

(ii) *Association to partnership*. If an eligible entity classified as an association elects under paragraph (c)(1)(i) of this section to be classified as a partnership, the following is deemed to occur: The association distributes all of its assets and liabilities to its shareholders in liquidation of the association, and immediately thereafter, the shareholders contribute all of the distributed assets and liabilities to a newly formed partnership.

(iii) *Association to disregarded entity*. If an eligible entity classified as an association elects under paragraph (c)(1)(i) of this section to be disregarded as an entity separate from its owner, the following is deemed to occur: The association distributes all of its assets

and liabilities to its single owner in liquidation of the association.

(iv) *Disregarded entity to an association*. If an eligible entity that is disregarded as an entity separate from its owner elects under paragraph (c)(1)(i) of this section to be classified as an association, the following is deemed to occur: The owner of the eligible entity contributes all of the assets and liabilities of the entity to the association in exchange for stock of the association.

(2) *Effect of elective changes*. The tax treatment of a change in the classification of an entity for federal tax purposes by election under paragraph (c)(1)(i) of this section is determined under all relevant provisions of the Internal Revenue Code and general principles of tax law, including the step transaction doctrine.

(3) *Timing of election*. An election under paragraph (c)(1)(i) of this section that changes the classification of an eligible entity for federal tax purposes is treated as occurring at the start of the day for which the election is effective. Any transactions that are deemed to occur under this paragraph (g) as a result of a change in classification are treated as occurring immediately before the close of the day before the election is effective. For example, if an election is made to change the classification of an entity from an association to a partnership effective on January 1, the deemed transactions specified in paragraph (g)(1)(ii) of this section (including the liquidation of the association) are treated as occurring immediately before the close of December 31 and must be reported by the owners of the entity on December 31. As a result, the last day of the association's taxable year will be December 31 and the first day of the partnership's taxable year will be January 1.

(4) *Effective date*. This paragraph (g) applies to elections that are filed on or after the date the final regulations are published in the **Federal Register**.

(h) *Effective date*—(1) *In general*. Except as otherwise provided in this section, the rules of this section are applicable as of January 1, 1997.

* * * * *

**Michael P. Dolan,**

*Acting Commissioner of Internal Revenue.*

[FR Doc. 97–28165 Filed 10–27–97; 8:45 am]

BILLING CODE 4830–01–U

## DEPARTMENT OF THE TREASURY

## Fiscal Service

## 31 CFR Part 208

**RIN 1510–AA56**

## Management of Federal Agency Disbursements: Hearing in Los Angeles, CA

**AGENCY:** Financial Management Service, Fiscal Service, Treasury.

**ACTION:** Proposed rule; notice of public hearing.

**SUMMARY:** This document schedules an additional public hearing on proposed regulations relating to the government's use of electronic funds transfer to make all Federal payments, with the exception of tax refunds, after January 1, 1999.

**DATES:** There will be a public hearing in Los Angeles on Tuesday, December 9, 1997 beginning at 9:00 a.m. Requests to testify at the hearing and outlines of testimony must be received by December 1.

**ADDRESSES:** The public hearing in Los Angeles will be held at the Federal Reserve Bank. The Bank is located at 950 S. Grand Avenue, Los Angeles, California, 90015.

Send requests to testify and outlines of testimony to Martha Thomas-Mitchell. See **FOR FURTHER INFORMATION CONTACT.**

**FOR FURTHER INFORMATION CONTACT:** Martha Thomas-Mitchell at (202) 874–6757 or at Internet address martha.thomas-mitchell@fms.sprint.com. The following toll free number is also available for registration information and inquiries:

1–800–344–0218 (hours of operation are 7:00 a.m.—5:00 p.m. Pacific Standard Time). For general information on the proposed regulation, contact Robyn Schulhof at (202) 874–6754 or Diana Shevlin at (202) 874–7032.

**SUPPLEMENTARY INFORMATION:** A notice of proposed rulemaking appearing in the **Federal Register** on September 16, 1997 (62 FR 48714) announced that three public hearings would be held in Dallas, New York City, and Baltimore. This notice adds an additional hearing in Los Angeles.

Dated: October 23, 1997.

**Michael T. Smokovich,**

*Deputy Commissioner.*

[FR Doc. 97–28523 Filed 10–27–97; 8:45 am]

BILLING CODE 4810–35–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Health Care Financing Administration

## 42 CFR Chapter IV

**[HCFA–1007–N]**

## Medicare Program; Meetings of the Negotiated Rulemaking Committee on the Provider-sponsored Organization Solvency Standards

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Notice of meetings.

**SUMMARY:** In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces the dates and locations for the second through sixth meetings of the Negotiated Rulemaking Committee on the provider-sponsored organization (PSO) solvency standards. The purpose of this committee is to negotiate the development of an interim final rule establishing solvency standards for provider-sponsored organizations under Part C of the Medicare program, as statutorily-mandated by the Balanced Budget Act of 1997. These meetings are open to the public.

**DATES:** The five scheduled meetings will be held on November 12–14, 1997; December 3–5, 1997; January 6–8, 1998; January 27–29, 1998; and February 18–20, 1998. The hours of the meetings are 9:00 a.m. to 5:00 p.m. on the first two days of each meeting and 8:00 a.m. to 3:00 p.m. on the third day of each meeting.

**ADDRESSES:**

- November 12, 13, and 14, 1997, at The Phoenix Park Hotel, 520 N. Capitol St., NW, Washington, DC 20001; (202) 638–6900;
- December 3, 4, and 5, 1997, at the Holiday Inn Capitol, 550 C St., SW, Washington, DC 20024; (202) 479–4000;
- January 6, 7, and 8, 1998, at The Phoenix Park Hotel at the above address;
- January 27, 28, and 29, 1998, at The Phoenix Park Hotel; and
- February 18, 19, and 20, 1998, at The Phoenix Park Hotel.

**FOR FURTHER INFORMATION:** Inquiries regarding these meetings should be addressed to Maureen Miller, Health Care Financing Administration, Center for Health Plans and Providers, Room S3–21–17, 7500 Security Boulevard, Baltimore, Maryland 21244, (410) 786–1097.

**SUPPLEMENTARY INFORMATION:** The Balanced Budget Act (BBA) of 1997 establishes a new Medicare+Choice program under part C of title XVIII of the Social Security Act (the Act). Under this program, an eligible individual may elect to receive Medicare benefits through enrollment in a Medicare+Choice plan that has a contract with us, which may include a health plan offered by a provider-sponsored organization. The BBA establishes a definition of PSOs that will be further clarified in forthcoming regulations. Section 4001 of the BBA mandates an expedited and modified negotiated rulemaking process for establishing solvency standards for PSOs. The standards must be published as an interim final rule, subject to comment, by April 1, 1998.

Under the BBA, the Negotiated Rulemaking Committee is required to report to the Secretary by January 1, 1998, regarding its progress and whether it is likely to achieve consensus. The Committee is required to report its proposed standards to the Secretary by March 1, 1998. If, however, the Committee reports on January 1st that it has failed to make significant progress or that consensus is unlikely within the assigned time frame, the Committee will be terminated and publication of a rule will proceed using other rulemaking procedures.

The Committee held its first meetings on October 20, 21, and 22, 1997. At these meetings, presentations were made that related to health plan solvency, and the Committee discussed how to address the principal issues and how to proceed in developing solvency standards.

The announced future meetings are open to the public without advance registration. Public attendance at the meetings may be limited to space available. A summary of all proceedings will be available for inspection in room 309–G of the Department's offices at 200 Independence Avenue, SW, Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (Phone: (202) 690–7890), or can be accessed through the HCFA Internet site at http://www/hcfa.gov/medicare/mgdcar1.htm. Additional information related to the Committee will be available on the web site.

(Section 1851 of the Social Security Act (42 U.S.C. 1395w–21 and section 10(a) of Public Law 92–463 (5 U.S.C. App. 2, section 10(a)); 45 C.F.R. Part 11)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 24, 1997.

**Nancy-Ann Min DeParle,**

*Deputy Administrator, Health Care Financing Administration.*

[FR Doc. 97–28676 Filed 10–27–97; 8:45 am]

BILLING CODE 4120–01–P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

### 50 CFR Part 17

**RIN 1018–AE00**

### Endangered and Threatened Wildlife and Plants; Extension of Comment Period on Proposed Rule and Draft Environmental Impact Statement for Grizzly Bear Recovery in the Bitterroot Ecosystem

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** The Fish and Wildlife Service provides notice that the comment period is being extended on the proposed rule to establish a nonessential experimental population of grizzly bears in the Bitterroot Ecosystem. All interested parties that have not done so are invited to submit comments on this proposal.

**DATES:** Comments will be accepted until December 1, 1997.

**ADDRESSES:** Written comments and materials should be addressed to Dr. Christopher Servheen, U.S. Fish and Wildlife Service Project Leader, Bitterroot Grizzly Bear EIS, P.O. Box 5127, Missoula, Montana 59806.

**FOR FURTHER INFORMATION CONTACT:** Dr. Christopher Servheen, Grizzly Bear Recovery Coordinator (see **ADDRESSES** above), at telephone (406) 243–4903.

**SUPPLEMENTARY INFORMATION:**

### Background

The U.S. Fish and Wildlife Service (Service) proposes to reintroduce the grizzly bear (*Ursus arctos horribilis*), a threatened species, into east-central Idaho and a portion of western Montana. On July 2, 1997, the Service published a proposed rule (62 FR 35762) to establish a nonessential experimental population pursuant to section 10(j) of the Endangered Species Act of 1973, as amended. Grizzly bear populations have been extirpated from most of the lower 48 United States. They presently occur in populations in the Cabinet/Yaak ecosystem in northwestern Montana and north Idaho, the Selkirk ecosystem in north Idaho and northeastern Washington, the North Cascades ecosystem in northwestern Washington, the Northern Continental Divide ecosystem in Montana, and the Yellowstone ecosystem in Montana, Wyoming, and Idaho. The purpose of this reintroduction is to reestablish a viable grizzly bear population in the Bitterroot ecosystem in east-central Idaho and adjacent areas of Montana, one of six grizzly recovery areas identified in the Grizzly Bear Recovery Plan. Potential effects of this proposed rule are evaluated in a draft Environmental Impact Statement released concurrently with the publication of the proposed rule. This grizzly bear reintroduction does not conflict with existing or anticipated Federal agency actions or traditional public uses of wilderness areas or surrounding lands.

### Public Comments Solicited

The comment period on this proposal is scheduled to close on November 1, 1997. To accommodate verbal requests and because of the extensive interest in the proposal, the Service extends the comment period. Written comments may now be submitted until December 1, 1997, to the Service office identified in the **ADDRESSES** section above. All comments must be received before the close of the comment period to be considered.

### Author

The author of this notice is Olin Bray, U.S. Fish and Wildlife Service, P.O. Box 25486, DFC, Denver, CO 80225–0486; telephone (303) 236–7400, extension 249.

### Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: October 22, 1997.

**Ralph O. Morgenweck,**

*Regional Director, Denver, Colorado.*

[FR Doc. 97–28481 Filed 10–27–97; 8:45 am]

BILLING CODE 4310–55–M

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 600

**[Docket No. 970829214–7214–01; I.D. 082097B]**

**RIN 0648–AJ76**

### Magnuson-Stevens Act Provisions; Observer Health and Safety

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** NMFS extends for 30 days the comment period for the proposed rule about guidelines to ensure observer health and safety.

**DATES:** Comments must be received by November 21, 1997.

**ADDRESSES:** Send comments to Gary Matlock, Director, Office of Sustainable Fisheries, NMFS, 1315 East-West Highway, Silver Spring, MD 20910.

**FOR FURTHER INFORMATION CONTACT:** William J. Bellows, 301–713–2341.

**SUPPLEMENTARY INFORMATION:**

## Background

The Magnuson-Stevens Act, as amended (16 U.S.C. 1801 *et seq.*), the Marine Mammal Protection Act, as amended (16 U.S.C. 1361 *et seq.*), and the Atlantic Tunas Convention Act, as amended (16 U.S.C. 971 *et seq.*) authorize the Secretary of Commerce to station observers aboard commercial fishing vessels to collect required scientific data for the purposes of fishery and protected species conservation and management, monitoring incidental mortality and serious injury to marine mammals and to other species listed under the Endangered Species Act, and monitoring compliance with existing Federal regulations. In addition, pursuant to the South Pacific Tuna Act of 1988 (16 U.S.C. 973 *et seq.*), observers may be required in the South Pacific Tuna Fishery.

A proposed rule was published on September 22, 1997 (62 FR 49464), in which guidelines were proposed for the purpose of ensuring observer health and safety while aboard a vessel and at the time of boarding and disembarking. The 30-day comment period ended October 22, 1997. One comment was received; it requested an extension of the comment period.

NMFS is interested in receiving comments and is extending the comment period through November 21, 1997.

This notice's comment-period extension has been determined to be not significant for purposes of E.O. 12866.

Dated: October 21, 1997.

**Gary C. Matlock,**

*Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 97–28440 Filed 10–27–97; 8:45 am]

BILLING CODE 3510–22–F

# Notices

Federal Register

Vol. 62, No. 208

Tuesday, October 28, 1997

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

### Revision of the Land and Resources Plans for the Chippewa and Superior National Forest; Beltrami, Cass, Cook, Itasca, Koochiching, Lake and St. Louis Counties, Minnesota

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice; reopening of comment period on Notice of Intent.

**SUMMARY:** On August 29, 1997, the USDA-Forest Service published a Notice of Intent to prepare an Environmental Impact Statement for revising the Chippewa and Superior Land and Resource Management Plans. The Comment period on that notice closed on October 28, 1997. The Forest Service has reopened the comment period until November 28, 1997 to allow another thirty one days for public comment.

**EFFECTIVE DATES:** The Comment period will end on November 28, 1997.

**FOR FURTHER INFORMATION CONTACT:** For further information contact Duane Lula, Forest Planner, (218) 626–4383. TTY (218) 626–4399.

**SUPPLEMENTARY INFORMATION:** Send written comments on the Notice of Intent to: Forest Plan Revision, Chippewa and Superior National Forests, Route 3, Box 244, Cass Lake, MN 56633–8929. Direct electronic mail to: chippewa@northernnet.com (ATTN: Forest Plan Revision).

Dated: October 21, 1997.

**Robert T. Jacobs,**

*Regional Forester.*

[FR Doc. 97–28349 Filed 10–27–97; 8:45 am]

BILLING CODE 3410–11–M

## DEPARTMENT OF AGRICULTURE

### Sunshine Act Meeting

**AGENCY:** Rural Telephone Bank, USDA.

**ACTION:** Staff Briefing for the Board of Directors.

**TIME AND DATE:** 2 p.m., Wednesday, November 5, 1997.

**PLACE:** Room 5066, South Building, Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC.

**STATUS:** Open.

**MATTERS TO BE DISCUSSED:** General discussion involving the 1996 Telecom Act and universal service; the budget for FY 1998; directors' liability insurance; allowance for loan losses reserve; and administrative issues.

**ACTION:** Stockholders' Meeting.

**TIME AND DATE:** 10 a.m., Thursday, November 6, 1997.

**PLACE:** The Williamsburg Room, Room 104–A, Jamie L. Whitten Building, Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC.

**STATUS:** Open.

**MATTERS TO BE CONSIDERED:** The following matters have been placed on the agenda for the stockholders' meeting:

1. Call to order.
2. Establishment of a quorum.
3. Action on the November 16, 1994, Minutes.
4. Secretary's annual report on loans approved in FY 1997.
5. Treasurer's annual report on FY 1997.
6. New Business.
7. Adjournment.

**ACTION:** Regular Meeting of the Board of Directors.

**TIME AND DATE:** Immediately following the stockholders' meeting, Thursday, November 6, 1997.

**PLACE:** The Williamsburg Room, Room 104–A, Jamie L. Whitten Building, Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC.

**STATUS:** Open.

**MATTERS TO BE CONSIDERED:** The following matters have been placed on the agenda for the Board of Directors meeting:

1. Call to order.
2. Action on the August 22, 1997, Minutes.
3. Report on loans approved in fourth quarter FY 1997.
4. Summary of financial activity for fourth quarter FY 1997.
5. Consideration of modifications to the calculation for determining the allowance for loan losses reserve.
6. Establish date and location of next regular Board meeting.
7. Adjournment.

**CONTACT PERSON FOR MORE INFORMATION:** Robert Peters, Assistant Governor, Rural Telephone Bank, (202) 720–9554.

Dated: October 22, 1997.

**Adam Golodner,**

*Deputy Governor, Rural Telephone Bank.*

[FR Doc. 97–28595 Filed 10–24–97; 9:56 am]

BILLING CODE 3410–15–P

## COMMISSION ON CIVIL RIGHTS

### Agenda and Notice of Public Meeting of the Connecticut Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a conference of the Connecticut Advisory Committee to the Commission will convene at 9:00 a.m. and adjourn at 4:00 p.m. on Wednesday, November 12, 1997, and Thursday, November 13, 1997, at the Taurig Learning Center, Library Resource Room (Room 501), Naugatuck Valley Community-Technical College, 750 Chase Parkway, Waterbury, Connecticut 06708. The purpose of the conference is to bring together subject matter experts, civil rights leaders, and public officials to inform the Committee and the public on major civil rights issues and discuss their possible solutions.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson Neil Macy, 860–242–7287, planning subcommittee Chairperson Patrick J. Johnson, Jr., 860–242–9577, or Ki-Taek Chun, Director of the Eastern Regional Office, 202–376–7533 (TDD 202–376–8116). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, October 16, 1997.

**Carol-Lee Hurley,**

*Chief, Regional Programs Coordination Unit.*

[FR Doc. 97–28451 Filed 10–27–97; 8:45 am]

BILLING CODE 6335–01–P

## COMMISSION ON CIVIL RIGHTS

### Agenda and Notice of Public Meeting of the Idaho Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the Idaho Advisory Committee to the Commission will convene at 1:00 p.m. and adjourn at 5:00 p.m. on November 7, 1997, at the Best Western Burley Inn, 800 North Overland Avenue, Burley, Idaho 83318. The purpose of the meeting is to hear presentations on problems which Hispanics are encountering in the Cassia County area.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson Rudolph Wilson, 208–336–4949, or Philip Montez, Director of the Western Regional Office, 213–894–3437 (TDD 213–894–3435). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, October 14, 1997.

**Carol-Lee Hurley,**

*Chief, Regional Programs Coordination Unit.*

[FR Doc. 97–28447 Filed 10–27–97; 8:45 am]

BILLING CODE 6335–01–P

## COMMISSION ON CIVIL RIGHTS

### Agenda and Notice of Public Meeting of the Kansas Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the Kansas Advisory Committee to the Commission will convene at 8:00 a.m. and adjourn at 12:30 p.m. on Thursday, November 20, 1997, at the State Capitol, 300 S.W. 10th Street, Room 313–S, Topeka, Kansas 66603. The purpose of the meeting is planning and to hold a briefing on equal employment opportunity in State government.

Persons desiring additional information, or planning a presentation to the Committee, should contact Melvin L. Jenkins, Director of the Central Regional Office, 913–551–1400 (TDD 913–551–1414). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, October 20, 1997.

**Carol-Lee Hurley,**

*Chief, Regional Programs Coordination Unit.*

[FR Doc. 97–28452 Filed 10–27–97; 8:45 am]

BILLING CODE 6335–01–P

## COMMISSION ON CIVIL RIGHTS

### Agenda and Notice of Public Meeting of the Mississippi Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the Mississippi Advisory Committee to the Commission will convene at 6:00 p.m. and adjourn at 8:00 p.m. on Thursday, November 20, 1997, at the Holiday Inn-Vicksburg, 3330 Clay Street, Vicksburg, Mississippi 39180. The Committee will reconvene at 8:30 a.m. and adjourn at 12:00 p.m. on Friday, November 21, 1997. The purpose of the meeting is to discuss a draft report and plan future activities.

Persons desiring additional information, or planning a presentation to the Committee, should contact Melvin L. Jenkins, Director of the Central Regional Office, 913–551–1400 (TDD 913–551–1414). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, October 14, 1997.

**Carol-Lee Hurley,**

*Chief, Regional Programs Coordination Unit.*

[FR Doc. 97–28447 Filed 10–27–97; 8:45 am]

BILLING CODE 6335–01–P

## COMMISSION ON CIVIL RIGHTS

### Agenda and Notice of Public Meeting of the New Hampshire Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the New Hampshire Advisory Committee to the Commission will convene at 9:00 a.m. and adjourn at 12:30 p.m. on Monday, November 17, 1997, at the Law Offices of Nixon, Raiche, Manning and Branch, 77 Central Street, Manchester, New Hampshire 03101. The purpose of the meeting is to discuss and plan future activities.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson Robert Raiche, 603–669–7070, or Ki-Taek Chun, Director of the Eastern Regional Office, 202–376–7533 (TDD 202–376–8116). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, October 15, 1997.

**Carol-Lee Hurley,**

*Chief, Regional Programs Coordination Unit.*

[FR Doc. 97–28450 Filed 10–27–97; 8:45 am]

BILLING CODE 6335–01–P

## COMMISSION ON CIVIL RIGHTS

### Agenda and Notice of Public Meeting of the Utah Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the Utah Advisory Committee to the Commission will convene at 6:00 p.m. and adjourn at 8:00 p.m. on Thursday, November 6, 1997, at the Hilton Hotel, 150 West 500 South, Salt Lake City, Utah 84101. The purpose of the meeting is to discuss the status of the employment discrimination project, and plan future program activities.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson Michael N. Martinez, 801–261–8169, or John Dulles, Director of the Rocky Mountain Regional Office, 303–866–1400 (TDD 303–866–1049). Hearing-impaired

persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, October 14, 1997.

**Carol-Lee Hurley,**

*Chief, Regional Programs Coordination Unit.*

[FR Doc. 97–28449 Filed 10–27–97; 8:45 am]

BILLING CODE 6335–01–P

## COMMISSION ON CIVIL RIGHTS

### Agenda and Notice of Public Meeting of the West Virginia Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the West Virginia Advisory Committee to the Commission will convene at 12:45 p.m. and adjourn at 4:30 p.m. on Wednesday, November 19, 1997, at the Raleigh County Public Library, 221 N. Kanawha Street, Beckley, West Virginia 25801. The purpose of the meeting is to plan its project activity for FY '97–98, and receive information from invited guests on civil rights issues in Beckley, West Virginia.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson Gregory T. Hinton, 304–367–4244, or Ki-Taek Chun, Director of the Eastern Regional Office, 202–376–7533 (TDD 202–376–8116). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, October 20, 1997.

**Carol-Lee Hurley,**

*Chief, Regional Programs Coordination Unit.*

[FR Doc. 97–28453 Filed 10–27–97; 8:45 am]

BILLING CODE 6335–01–P

## DEPARTMENT OF COMMERCE

### Bureau of the Census

**[Docket No. 961213356–7236–02]**

### Census Tract Program for Census 2000—Final Criteria

**AGENCY:** Bureau of the Census, Commerce.

**ACTION:** Notice of final program.

**SUMMARY:** Census tracts are relatively permanent small-area geographic divisions of a county or statistically equivalent entity [1] defined for the tabulation of decennial census data and selected other statistical programs. The primary goal of the census tract program is to provide a geographic unit that has stable boundaries between decennial censuses. Other goals include the identification of geographic areas that represent meaningful geographic divisions of a county based on economic or social interaction, significant topographic differences within a county, or a certain degree of demographic homogeneity at the time of original delineation. The Census Bureau uses census tracts to tabulate and disseminate a wide variety of data. For Census 2000, census tracts will be established across the entire area of the United States, Puerto Rico, and the Island Areas (American Samoa, Guam, the Northern Mariana Islands, and the Virgin Islands of the United States).

Census tracts first appeared in the 1910 census when local officials in eight of the larger cities delineated these areas. In the 1910, 1920, and 1930 censuses, the Census Bureau published census tract data as special tabulations; in 1940, the Census Bureau began including census tract data in its standard publications. The number of data subjects and the amount of data, as well as the number of counties containing census tracts, increased in every census through 1990. For the 1990 census, the Census Bureau inaugurated complete nationwide coverage and statistics for census tracts or statistically equivalent entities known as block numbering areas (BNAs). For Census 2000, the Census Bureau will combine the similar programs into a single census tract program.

To determine the boundaries and identification numbers of census tracts, the Census Bureau offers a program to local participants, such as locally identified agencies and American Indian tribal officials, whereby they can review and update the boundaries of the census tracts and BNAs delineated for the 1990 census and suggest revisions according to the criteria developed and promulgated by the Census Bureau. The Census Bureau will then review the resulting Census 2000 census tract plans for conformance to these criteria. The Census Bureau does not take into account or attempt to anticipate any nonstatistical uses that may be made of census tracts, nor will the Census Bureau modify the definition of census tracts to meet the requirements of any nonstatistical program.

The Census Bureau is now publishing final criteria for the delineation of census tracts for Census 2000. These criteria will apply to the 50 states, the District of Columbia, American Indian and Alaska Native areas, Puerto Rico, and the Island Areas. The Census Bureau may modify and, if necessary, reject proposals for census tracts that do not meet the criteria established following this notice.

In addition to these final criteria, this notice includes a description of the changes from the criteria used for the 1990 census and a list of definitions of key terms used in the criteria.

**EFFECTIVE DATE:** The census tract criteria for Census 2000 become effective November 28, 1997.

**FOR FURTHER INFORMATION CONTACT:** Dr. Joel Morrison, Chief, Geography Division, Bureau of the Census, Washington, DC 20233–7400, telephone (301) 457–1132, or e-mail (joel.morrison@geo.census.gov).

**SUPPLEMENTARY INFORMATION:** The census tract delineation criteria have evolved over the past nine decades in response to decennial census practices and the preferences of local participants and data users. After each decennial census, the Census Bureau, in consultation with past participants and data users, reviews and revises these criteria. Then, before the next decennial census, the Census Bureau offers state, tribal, and local officials an opportunity to correct, update, and otherwise improve the universe of census tracts.

In July and August 1995, the Census Bureau issued invitations to local groups and agencies to participate in the delineation of statistical geographic areas for Census 2000. These groups and agencies included regional planning agencies, councils of governments, county planning agencies, officials of

[1] Includes parishes in Louisiana; boroughs and census areas in Alaska; independent cities in Maryland, Missouri, Nevada, and Virginia; that portion of Yellowstone National Park in Montana; districts/islands in American Samoa, the main islands of the Virgin Islands of the United States; municipalities in the Northern Mariana Islands; municipios in Puerto Rico; the entire area constituting the District of Columbia; and the entire area constituting Guam. This notice will refer to all these entities collectively as ''counties.''

Federally recognized American Indian tribes, and officials of the 12 nonprofit Alaska Native Regional Corporations.

By early 1998, the Census Bureau will provide maps and detailed guidelines to program participants for the review and delineation of census tracts for Census 2000.

**Response to Comments**

The Census Bureau issued a Notice of Proposed Program Revisions and Request for Comments in the **Federal Register** (62 FR 4246) on Wednesday, January 29, 1997. That notice solicited comments on the proposed criteria for delineating census tracts for Census 2000. The Census Bureau did not receive any comments in response to that **Federal Register** notice and, therefore, is making no substantive changes to the criteria for this program.

**Executive Order 12866**

This notice does not meet the criteria for a ''significant regulatory action'' as specified in Exective Order 12866.

**Regulatory Flexibility Act**

Pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Assistant General Counsel for Legislation and Regulation, Department of Commerce, certified to the Chief Counsel, Small Business Administration, that this notice will not have a significant economic impact on a substantial number of small entities. The notice sets forth the criteria for the delineation of census tracts for Census 2000. The criteria will be used to determine boundaries for small-area geographic divisions of a county or other statistically relevant entity defined for the tabulation of census data. The Census Bureau uses census tracts to tabulate and disseminate a wide variety of statistical data from the decennial census. Thus, because the delineation of census tracts is solely for statistical purposes to enable the Census Bureau to tabulate and publish data for Census 2000, it will not have a significant economic impact on a substantial number of small entities.

**Final Program Requirements**

*A. Criteria for Delineating Census Tracts for Census 2000*

The Census Bureau announces the following final criteria for use in delineating Census 2000 census tracts.

1. General Characteristics

- A census tract must meet the population and boundary feature criteria and comprise a reasonably compact, continuous land area internally accessible to all points by road; the only exceptions are:

(a) where the tract is defined to include a specific legal or land-use area that itself is discontinuous, in which case discontinuity is allowed at the discretion of the Census Bureau.

(b) where a discontinuous area or inaccessible area would not meet population size requirements for a separate census tract, in which case the discontinuous or inaccessible area must be combined within an adjacent or proximate census tract.

(c) where the topography or geographic patterns of settlement are not compact, but are irregularly shaped, in which case a census tract shape can depart from the compactness requirement.

- A county boundary always must be a census tract boundary. This criterion takes precedence over all other criteria or requirements except for the population threshold criteria for census tracts on American Indian reservations (AIRs) in multiple counties.
- Census tracts must cover the entire land and inland water area of each county. In coastal waters, territorial seas, and the Great Lakes, the Census Bureau recommends creating in each county a single census tract covering such water bodies to provide for complete census tract coverage.

2. Identification

- A census tract has a basic census tract number composed of no more than four digits and may have a two-digit decimal suffix.
- Census tract numbers must be unique within each county.
- The range of acceptable basic census tract numbers for Census 2000 is 1 to 9989; census tracts delineated specifically to complete coverage in territorial seas and the Great Lakes will use the number 0000 in each county.
- Census tracts delineated within or to encompass an AIR that crosses county or state and county boundaries, where the intent is for the census tract to ignore the county or state boundary for tabulation in an American Indian geographic hierarchy, will use numbers 9400 to 9499.
- The range of acceptable census tract suffixes is .01 to .98. The Census Bureau reserves the .99 suffix to identify civilian and military ships as ''crews-of-vessels'' census tracts.

3. Boundary Features

The Census Bureau recommends that most census tract boundaries follow visible and identifiable features. This makes the location of census tract boundaries less ambiguous. The Census Bureau also permits the use of legal boundaries in some states and situations to allow for census tract-to-governmental unit relationships where the governmental boundaries tend to remain unchanged between censuses. The following features are acceptable as census tract boundaries for Census 2000:

- All state and county boundaries (always required).
- Visible, perennial natural and cultural features, such as roads, rivers, canals, railroads, above-ground high-tension power lines, and so forth.
- All minor civil division (MCD) boundaries (generally towns or townships) in Connecticut, Indiana, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.
- Those MCD boundaries not coincident with the boundaries of incorporated places that themselves are MCDs (being either coextensive with an MCD or independent of MCDs) in Illinois (townships only, not election precincts), Iowa, Kansas, Michigan, Minnesota, Missouri (governmental townships only), Nebraska (townships only, not election precincts), North Dakota, Ohio, South Dakota, and Wisconsin.
- Barrio, barrio-pueblo, and subbarrio boundaries in Puerto Rico, census subdistrict boundaries in the Virgin Islands of the United States, MCD-county and island boundaries in American Samoa, municipal district boundaries in the Northern Mariana Islands, and election district boundaries in Guam.
- All incorporated place boundaries in Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.
- Conjoint incorporated place boundaries in other states; that is, the boundary separating two different incorporated places.
- American Indian reservation and trust land boundaries.
- Alaska Native village statistical areas and Alaska Native Regional Corporation boundaries, at the discretion of the Census Bureau, insofar as such boundaries are unambiguous for allocating living quarters as part of Census 2000 activities.

When the features listed above are not available for selection, the Census Bureau may, at its discretion, approve other nonstandard visible features, such as ridge lines, pipelines, intermittent streams, fence lines, and so forth. The Census Bureau also may accept, on a case-by-case basis, the boundaries of selected nonstandard and potentially

nonvisible features such as the boundaries of national parks and national forests, cemeteries, or other special land-use properties, the straight-line extensions of visible features, and other lines of sight.

4. Population Thresholds

The Census Bureau proposes the following population criteria for census tracts (see Table 1):

- In the United States, Puerto Rico, and the Virgin Islands of the United States: 1,500 to 8,000 inhabitants, with an optimum of 4,000 inhabitants.
- In American Samoa, Guam, and the Northern Mariana Islands: 1,500 to 8,000 inhabitants, with an optimum of 2,500 inhabitants.
- On American Indian reservations: 1,000 to 8,000 inhabitants, with an optimum of 2,500 inhabitants. (The population criteria for American Indian reservations apply to the entire reservation, including American Indian reservations in multiple counties or states.)
- In all counties, for census tracts delineated to enclose an institution, a military installation, or other ''special place'' population: at least 1,000 inhabitants, with no optimum average or maximum (no change from 1990). (A special place includes facilities with resident population, such as correctional institutions, military installations, college campuses, workers' dormitories, hospitals, nursing homes, and group homes. A special place includes the entire facility including nonresidential areas and staff housing units, as well as all group quarters population.)

TABLE 1.—POPULATION THRESHOLDS FOR CENSUS 2000 CENSUS TRACTS

| Area description | Population thresholds | | |
|---|---|---|---|
| | Optimum | Minimum | Maximum |
| United States, Puerto Rico, Virgin Islands of the U. S. | 4,000 | 1,500 | 8,000 |
| American Samoa, Guam, Northern Mariana Islands | 2,500 | 1,500 | 8,000 |
| American Indian reservation | 2,500 | 1,000 | 8,000 |
| Special place census tract | none | 1,000 | none |

5. Comparability and Implementation

As in previous censuses, the Census Bureau generally will not accept newly proposed census tracts that do not meet the required minimum population. However, with appropriate justification, the Census Bureau may grant exceptions on a case-by-case basis. For example, to facilitate census tract comparability over time, any 1990 census tract or BNA (except a ''sliver'' census tract/BNA—see 6. Sliver Census Tracts) that is virtually unchanged (that is, having less than five percent of the 1990 population affected by a boundary revision) may be recognized as a Census 2000 census tract even if its population falls below the minimum required population or above the maximum allowable population. The Census Bureau, however, recommends combining low population census tracts and splitting large population census tracts to meet the goal of providing meaningful small-area data.

6. Sliver Census Tracts

The Census Bureau will not retain, or continue to recognize for Census 2000, any 1990 ''sliver'' census tracts or BNAs. After the Census Bureau inserted the 1990 census tracts into the Topologically Integrated Geographic Encoding and Referencing System (TIGER) database, sliver census tracts resulted from:

- County boundary changes or corrections.
- Special land-use boundary changes or corrections (military reservations, national parks, and so forth).
- Local requests to correct errors in the insertion of 1990 areas into the TIGER database.

Sliver census tracts usually cover a very small area, and in most cases involve little or no population or housing. The Census Bureau has adopted new rules for establishing tabulation geographic areas in Census 2000 by separating the collection areas from the tabulation areas. This change will eliminate the need for such sliver census tracts in Census 2000.

In 1990, the Census Bureau established rules to assign special numerical suffixes to identify sliver census tracts, generally beginning with .98 and continuing in descending order. The Census Bureau applied the suffix to both the original census tract that lost territory and the newly created sliver census tract. For Census 2000, we recommend that local participants dispense with the sliver suffix for legitimate census tracts, but will not require a change if specifically requested by the local participant for comparability purposes.

*B. Changes to the Criteria for Census 2000*

Most provisions of the census tract criteria remain unchanged from those used in conjunction with the 1990 census, with the few exceptions summarized below:

1. The Census Bureau is combining the census tract and BNA programs to create a single census tract program. The major differences between the 1990 census tracts and BNAs were: (1) representatives of the states or Census Bureau staff were responsible for the delineation of BNAs rather than local census statistical areas committees, and (2) census tracts were delineated mainly according to population criteria, while BNAs were delineated to meet data collection criteria based on the number of housing units rather than population. For Census 2000, the Census Bureau will contact local officials for the delineation of census tracts, and there will not be a housing unit criterion, thus bringing both areas under a single standard.

2. The Census Bureau is increasing the number of governmental units that have boundaries acceptable to use as census tract boundaries. The added areas are: all MCDs in Indiana and selected MCDs in Illinois, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, South Dakota, and Wisconsin; the MCD-county and island areas of American Samoa; and villages in New York.

3. The Census Bureau now allows officials of Federally recognized American Indian reservations meeting the 1,000 minimum population threshold to delineate census tracts without regard to state or county boundaries. Although the Census Bureau will tabulate data for each state-county-census tract part, it also plans to provide summed data for all components of each census tract bearing the same numeric identifier within a Federally recognized AIR.

4. The Census Bureau will use census tracts only as tabulation areas, thus allowing late corrections to census tract boundaries as a result of legal county

boundary changes or to correct errors without having to create unique sliver census tracts for such areas.

Definitions of Key Terms

*Alaska Native Regional Corporation (ANRC)*—A corporate entity established under the Alaska Native Claims Settlement Act of 1972, Public Law 92–203, as amended by Public Law 92–204, to conduct both the business and nonprofit affairs of Alaska Natives. Twelve ANRCs cover the entire State of Alaska except for the Annette Islands Reserve.

*Alaska Native village statistical area (ANVSA)*—A statistical entity containing the densely settled extent of an Alaska Native village that constitutes an association, band, clan, community, group, tribe, or village recognized pursuant to the Alaska Native Claims Settlement Act of 1972, Public Law 92–203, as amended by Public Law 92–204.

*American Indian reservation (AIR)*—A Federally recognized American Indian entity with boundaries established by treaty, statute, and/or executive or court order and over which American Indians have governmental jurisdiction. Along with reservations, designations such as colonies, communities, pueblos, rancherias, and reserves apply to American Indian reservations.

*Block numbering area (BNA)*—A small-area, statistical geographic division of a county or statistically equivalent area delineated in 1990 instead of and generally geographically equivalent to census tracts. For Census 2000, the Census Bureau is merging the BNA program into the census tract program.

*Coastal water*—Water bodies between territorial seas and inland water, the encompassing headlands being more than one mile apart and less than 24 miles apart.

*Conjoint*—A description of a boundary shared by two adjacent geographic entities.

*Continuous*—A description of areas sharing common boundaries, such that the areas, when combined, form a single piece of territory. Discontinuous areas form disjoint pieces.

*Crews-of-vessels census tract*—A census tract created at the time of enumeration for allocating the shipboard population of merchant and military ships and identified with a special numeric suffix equal to .99.

*Great Lakes' waters*—Water area beyond one mile wide headland embayments located in any of the five Great Lakes: Erie, Huron, Michigan, Ontario, or Superior.

*Incorporated place*—A type of governmental unit, sanctioned by state law as a city, town (except in New England, New York, and Wisconsin), village, or borough (except in Alaska and New York), having legally prescribed limits, powers, and functions.

*Inland water*—Water bodies entirely surrounded by land or at the point where their opening to coastal waters, territorial seas, or the Great Lakes is less than one mile across.

*Minor civil division (MCD)*—The primary governmental or administrative division of a county in 28 states, Puerto Rico and the Island Areas having legal boundaries, names, and descriptions. MCDs represent many different types of legal entities with a wide variety of characteristics, powers, and functions depending on the state and type of MCD. In some states, some or all of the incorporated places also constitute MCDs.

*Nonvisible feature*—A map feature that is not visible on the ground such as a city or county boundary through space, a property line, a short line-of-sight extension of a road, or a point-to-point line of sight.

*Special place*—A specific location requiring special enumeration because the location includes people not in households or the area includes special land use. Special places include facilities with resident populations, such as correctional institutions, military installations, college campuses, workers' dormitories, hospitals, nursing homes, group homes, and land-use areas such as national parks. A special place includes the entire facility, including nonresidential areas and staff housing units, as well as all group quarters population.

*Territorial seas*—Water bodies not included under the rules for inland water, coastal water, or Great Lakes' waters, see above.

*Visible feature*—A map feature that one can see on the ground such as a road, railroad track, above-ground transmission line, stream, shoreline, fence, sharply defined mountain ridge, or cliff. A nonstandard visible feature is a feature that may not be clearly defined on the ground (such as a ridge), may be seasonal (such as an intermittent stream), or may be relatively impermanent (such as a fence). The Census Bureau generally requests verification that nonstandard features pose no problem in their location during field work.

Dated: October 10, 1997.

**Martha Farnsworth Riche,**

*Director, Bureau of the Census.*

[FR Doc. 97–28430 Filed 10–27–97; 8:45 am]

BILLING CODE 3510–07–P

## DEPARTMENT OF COMMERCE

## Economic Development Administration

## Notice of Petitions by Producing Firms for Determination of Eligibility to Apply for Trade Adjustment Assistance

**AGENCY:** Economic Development Administration (EDA).

**ACTION:** To give firms an opportunity to comment.

Petitions have been accepted for filing on the dates indicated from the firms listed below.

LIST OF PETITION ACTION BY TRADE ADJUSTMENT ASSISTANCE FOR PERIOD 09/21/97–09/17/97

| Firm name | Address | Date petition accepted | Product |
|---|---|---|---|
| Stanwood Mills, Inc | P.O. Box 195, Fairview Avenue, Slatington, PA 18080. | 09/30/97 | Greige Goods (Unbleached Fabric of Acetate, Rayon and Polyester). |
| G.L. Industries of Indiana, Inc | 2860 North National Road, Columbus, IN 47201. | 09/30/97 | Injection Molded Plastic Television Cabinets. |
| Quality Capabilities, Inc | 15251 Roosevelt Blvd, Suite 207, Clearwater, FL 34620. | 10/03/97 | Printed Circuit Assemblies. |
| Colt Technology Corporation | 800 NW Technology Dr., Lees Summit, MO 64086. | 10/03/97 | Printed Circuit Boards without any Electronic Components Attached. |
| American Wilcon Plastics, Inc | 418 North Front Street, Orrick, MO 64077. | 10/03/97 | Plastic Injection Molded Kitchen Wares and Other Misc. Plastic Molded Parts. |

LIST OF PETITION ACTION BY TRADE ADJUSTMENT ASSISTANCE FOR PERIOD 09/21/97–09/17/97—Continued

| Firm name | Address | Date petition accepted | Product |
|---|---|---|---|
| Bethel Furniture Stock, Inc | 515 West Bethel Road, Bethel, ME 04217. | 10/03/97 | Wood Furniture Panels and Bends. |
| R.S. Owens & Co., Inc | 5535 North Lynch Avenue, Chicago, IL 60630. | 10/03/97 | Award Items (Trophies, Plaques, Figures/Statuettes, Cups/Bowls, Medals/Pins and Related Components). |
| Christina J. Manufacturing, Inc | 85 Tenth Avenue, New York, NY 10011. | 10/10/97 | Women's Sportswear Including Dresses, Blouses, Suits and Jackets. |
| American Louvered Products Co. | 4910 W. Knollwood Street, Tampa, FL 33634. | 10/10/97 | Wooden Louvered Interior Doors. |
| Missouri Table and Chair Company. | 2055 NE Independence, Lee's Sumit, MO 64064. | 10/10/97 | Wooden Furniture (Kitchen Dining Tables, Chairs, Computer Desks, and End Tables). |
| Cambord, Inc | 38 Jackson Street, Hoboken, NJ 07030. | 10/17/97 | Wallpaper Silk Screened By Hand. |
| Joey Oysters, Inc | P.O. Box 904, Amite, LA 70422. | 10/17/97 | Fresh Shucked Oysters. |
| Apparel Technologies, Inc | 2330 South Eastern Avenue, Commerce, CA 90040. | 10/17/97 | Women's Apparel (Skirts, Pants, Tops and Jackets), and Store Display Fixtures. |

The petitions were submitted pursuant to Section 251 of the Trade Act of 1974 (19 U.S.C. 2341). Consequently, the United States Department of Commerce has initiated separate investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each firm contributed importantly to total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

Any party having a substantial interest in the proceedings may request a public hearing on the matter. A request for a hearing must be received by Trade Adjustment Assistance, Room 7315, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than the close of business on the tenth calendar day following the publication of this notice.

The Catalog of Federal Domestic Assistance official program number and title of the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance.

Dated: October 21, 1997.

**Anthony J. Meyer,**

*Coordinator, Trade Adjustment and Technical Assistance.*

[FR Doc. 97–28478 Filed 10–27–97; 8:45 am]

BILLING CODE 3510–24–M

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–405–802]**

### Certain Cut-to-Length Carbon Steel Plate From Finland: Amended Final Determination of Sales at Less Than Fair Value

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of final court decision and amended final determination of sales at less than fair value.

**EFFECTIVE DATE:** October 28, 1997.

**FOR FURTHER INFORMATION CONTACT:** Daniel Manzoni or David J. Goldberger, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone (202) 482–1121 or (202) 482–4136, respectively.

**SUMMARY:** On May 13, 1997, the Court of International Trade affirmed the Department of Commerce's final remand results in Rautaruukki Oy v. United States, Consol. Court No. 93–09–00560–AD, arising out of the Department's final determination of sales at less than fair value in the antidumping investigation of certain cut-to-length carbon steel plate from Finland. As there is now a final and conclusive court decision in this action, we are amending our final determination of sales at less than fair value and we will instruct the U.S. Customs Service to change the appropriate cash deposit rate.

**SUPPLEMENTARY INFORMATION:**

#### Background

On July 9, 1993, the Department of Commerce (the Department) published its final determination in its investigation of sales at less than fair value (LTFV) of certain cut-to-length carbon steel plate from Finland (58 FR 37122). On August 19, 1993, the Department published an amended final determination (58 FR 44165).

Subsequently, respondent Rautauruukki Oy and petitioner Inland Steel Industries, Inc, and a number of other interested parties, filed lawsuits with the Court of International Trade (the Court) challenging the final determination. On March 31, 1995, the Court remanded the case to the Department and ordered the Department to recalculate the value added tax (VAT) according to the Department's new methodology. *See* Rautaruukki Oy v. United States, Slip Op. 95–56, (CIT, March 31, 1995). Specifically, the Court ordered that the Department revise its dumping margin calculation by multiplying the Finnish VAT rate by United States price (USP) and then increasing USP by the resulting amount.

On remand, in accordance with Federal-Mogul Corp. and The Torrington Co. v. United States, Slip Op. 93–194 (CIT, October 7, 1993), the Department recalculated the margins in this case by applying the foreign market tax rate to the price of the United States merchandise at the same point in the chain of commerce that the foreign market tax was applied to foreign market sales.

On May 13, 1997, the Court affirmed the final remand results. *See* Rautaruukki Oy v. United States, Slip Op. 97–56 (CIT, May 13, 1997). As there is now a final and conclusive court

decision in this action we are amending our final determination, and we will subsequently instruct the U.S. Customs Service to change the appropriate cash deposit requirements entries subject to this investigation.

### Amendment to Final Determination

Pursuant to 516A(e) of the Tariff Act of 1930, as amended, (the Act) we are now amending the final results of this investigation of certain cut-to-length carbon steel plate from Finland.

The recalculated weighted-average margins are as follows:

| Producer/manufacturer/exporter | Margin percentage |
|---|---|
| Rautaruukki Oy | 40.36 |
| All Others | 40.36 |

In August 1993, the U.S. International Trade Commission (the Commission) determined that imports of certain cut-to-length carbon steel plate from Finland materially injure a U.S. industry. As a consequence of the Commission's affirmative determination, these products were subject to an antidumping duty order. Since publication of the LTFV final determination and order, the Department has completed, pursuant to Section 751 of the Act, first and second administrative reviews of the antidumping order. As a result, this amended final determination does not necessitate a change in cash deposit rates nor liquidation of the subject merchandise as the order relates to Rautaruukki Oy. However, the Department will instruct the U.S. Customs Service to change the appropriate cash deposit requirements to 40.36 percent of the entered value of the subject merchandise for all other producers/exporters.

Dated: October 22, 1997.

**Robert S. LaRussa,**

*Assistant Secretary for Import Administration.*

[FR Doc. 97–28542 Filed 10–27–97; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

## International Trade Administration

## Export Trade Certificate of Review

**ACTION:** Notice of issuance of an amended Export Trade Certificate of Review, Application No. 84–8A012.

**SUMMARY:** The Department of Commerce has issued an amendment to the Export Trade Certificate of Review granted to Northwest Fruit Exporters (''NFE'') on June 11, 1984. Notice of issuance of the Certificate was published in the **Federal Register** on June 14, 1984 (49 FR 24581).

**FOR FURTHER INFORMATION CONTACT:** Morton Schnabel, Acting Director, Office of Export Trading Company Affairs, International Trade Administration, (202) 482–5131. This is not a toll-free number.

**SUPPLEMENTARY INFORMATION:** Title III of the Export Trading Company Act of 1982 (15 U.S.C. Sections 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. The regulations implementing Title III are found at 15 CFR part 325 (1997).

The Office of Export Trading Company Affairs (''OETCA'') is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Department of Commerce to publish a summary of a Certificate in the **Federal Register**. Under Section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

### Description of Amended Certificate

Export Trade Certificate of Review No. 84–00012, was issued to NFE on June 11, 1984 (49 FR 24581, June 14, 1984) and previously amended on May 2, 1988 (53 FR 16306, May 6, 1988); September 21, 1988 (53 FR 37628, September 27, 1988); September 20, 1989 (54 FR 39454, September 26, 1989); November 19, 1992 (57 FR 55510, November 25, 1992); August 16, 1994 (59 FR 43093); and November 4, 1996 (61 FR 57850, November 8, 1996).

NFE's Export Trade Certificate of Review has been amended to:

1. Add each of the following companies as a new ''Member'' of the Certificate within the meaning of section 325.2(1) of the Regulations (15 C.F.R. 325.2(1)): D & G Packing Inc., Plymouth, Washington; Fox Orchards, Mattawa, Washington; J.C. Watson Company, Parma, Idaho; Jenks Bros. Cold Storage, Inc., Royal City, Washington; Monson Fruit Co., Selah, Washington; Poirier Packing & Warehouse, Pateros, Washington; and Williamson Orchards, Caldwell, Idaho;

2. Delete the following companies as a ''Members'' of the Certificate: Dole Northwest, Wenatchee, Washington; and Sands Orchards, Inc., Emmett, Idaho; and

3. Change the listing of the company names for the current Members ''Roche Fruit Company, Inc.'' to the new listing ''Roche Fruit, Ltd.; and ''Stadelman Fruit, Inc.'' to ''Stadelman Fruit, L.L.C.''.

A copy of the amended certificate will be kept in the International Trade Administration's Freedom of Information Records Inspection Facility, Room 4102, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230.

Dated: October 22, 1997.

**Morton Schnabel,**

*Acting Director, Office of Export Trading Company Affairs.*

[FR Doc. 97–28547 Filed 10–27–97; 8:45 am]

BILLING CODE 3510–DR–P

## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

## Vessel Monitoring and Communications Requirements

**ACTION:** Proposed collection; Comment request

**SUMMARY:** The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

**DATES:** Written comments must be submitted on or before December 29, 1997.

**ADDRESSES:** Direct all written comments to Linda Engelmeier, Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington DC 20230.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Robert B. Gorrell, F/SF3—Rm. 14603, 1315 East-West Highway, Silver Spring, Maryland 20910 (phone: 301–713–2343).

**SUPPLEMENTARY INFORMATION:**

### I. Abstract

This is a generic collection of information that includes regulatory requirements for vessel monitoring and communication under the authority of the Magnuson-Stevens Fishery Conservation and Management Act. Fishing vessels and/or at-sea processing vessels in selected fisheries are required to have installed transponders/vessel

tracking systems or Inmarsat Communication Units for onboard communications with the National Marine Fisheries Service. The primary purpose of such equipment is to communicate the vessel's location or, in the case of Inmarsat Communication Units, communicate harvest information collected by observers aboard the vessel. The installation time of the monitoring and/or communication equipment is measured as well as the estimated transmission times for communication.

## II. Method of Collection

Real-time vessel location information is collected by querying the transponders and vessel monitoring system units on board the fishing vessels and/or at-sea processing vessels. This method of collection obviates the need for a more costly and problematic requirement that vessel operators report vessel location. Other information on harvest is electronically communicated by NMFS observers on-board fishing vessels. Net-sounder devices are also used to collect data on certain trawl gear.

## III. Data

*OMB Number:* 0648–0307.

*Form Number:* N/A.

*Type of Review:* Regular Submission.

*Affected Public:* Owners and operators of fishing vessels and at-sea processing vessels.

*Estimated Number of Respondents:* 861 (150 multispecies vessels, 250 scallop vessels, 190 groundfish at-sea processing vessels, 100 groundfish trawlers around Kodiak, 165 pelagics vessels, and 6 crustaceans vessels)

*Estimated Time Per Response:* This varies with type of equipment and requirement. Upon installation, vessel monitoring or transponder systems automatically transmit date, which takes about 5 seconds. For requirements to transmit data on Inmarsat communications units, transmissions take about 10 minutes.

*Estimated Total Annual Burden Hours:* 9,642.

*Estimated Total Annual Cost to Public:* $1,408,696. Costs for these different monitoring and communication systems vary; some impose no direct costs on the vessel owners or operators.

Direct costs (actual or projected) to vessel owners or operators of VTS in the Atlantic Sea Scallop Fishery and in the Northeast Multispecies Fishery are, on average: (1) $7,000 per initial purchase and installation of transceiver/terminal and antenna; (2) $120 for basic monthly communications and messaging costs; and (3) $2,000 per year for repairs and maintenance (assuming antenna or other problems). Out of the 150 multispecies vessels and 250 scallop vessels potentially subject to VTS requirements under existing regulations, an estimated 5 multispecies vessels and 125 scallop vessels already have VTS installed. Therefore, annual installation costs would be $630,000 ($7,000 times 270 vessels annualized over the 3-year period of this information collection), annual communications and messaging costs would be $576,000 ($1,440 times 400 vessels), and annual repair and maintenance costs could be $160,000 ($2,000 times 20 percent of the 400 vessels). These costs total $1,366,000 annually. A requirement for VTS in the scallop and multispecies fisheries has been proposed, but is not mandatory at present.

Direct costs to industry for communication equipment for electronic reporting by observers in the Alaska Groundfish Fisheries are: (1) $30,000 per initial purchase and installation of INMARSAT Standard A units; and (2) $5,000 per initial purchase and installation of INMARSAT Standard C units. All but 12 of the approximately 190 at-sea processing vessels, affected by the requirement for electronic communication equipment to facilitate reporting of fisheries data by observers, are believed to have installed the required equipment. Annual installation costs would be $36,666 ($30,000 times 2 vessels installing Standard A units and $5,000 times 10 vessels installing Standard C units annualized over the 3-year period of this information collection). Costs of net-sounder devices on 100 groundfish trawlers around Kodiak Island are not included here because NMFS does not actually require their use although still in the regulations.

There are no direct costs to owners or operators of the 165 vessels in the Pelagic Fisheries of the Western Pacific because NMFS owns, installs, repairs, and maintains the VMS units. NMFS operation also includes the messaging costs.

Of the 15 permitted vessels in the limited entry Crustacean Fisheries of the Western Pacific Region, 9 also fish in the pelagic fishery and already carry VMS units. The owners or operators of the additional possible 6 lobster vessels would incur a direct cost of about $2,500 each for initial purchase of VMS units. Installation cost for each unit would be about $200. Therefore, annual purchase and installation costs would be $5,400 ($2,700 times 6 vessels annualized over the 3-year period of this information collection). Annual messaging costs would be about $270 for the fleet of 15 vessels (15 vessels times 30 days times 4 messages per day times $0.15 per message—assumes a 30-day season). Annual repair and maintenance costs for the 6 vessels is estimated at $360 ($60 times 6 vessels). These costs total $6,030 annually.

## IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: October 23, 1997.

**Linda Engelmeier,**

*Departmental Forms Clearance Officer, Office of Management and Organization.*

[FR Doc. 97–28494 Filed 10–27–97; 8:45 am]

BILLING CODE 3510–22–P

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## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

**[I.D. 101497E]**

## Protection of California Salmonids; Public Meeting and Availability of Draft Memorandum Of Understanding (MOU) Between the National Marine Fisheries Service and the State of California for Review and Comment

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice of public meeting and request for comments on draft MOU.

**SUMMARY:** NMFS, Southwest Region, in cooperation with the California Resources Agency, intends to hold a public meeting for the purpose of soliciting public input on development of a MOU between NMFS and the State of California (State). The purpose of the MOU is to seek an agreement with the State on a process that addresses the conservation of California's salmonids.

This agreement will define NMFS' relationship to the Governor's Watershed Restoration and Protection Council (WRPC).

**DATES:** The meeting date is November 12, 1997, 1:00–4:00 p.m. and 6:00–9:00 p.m. Written comments on the draft MOU must be received by November 28, 1997, to be considered during preparation of the final MOU.

**ADDRESSES:** Both meetings will be held at the State of California Building, Room 410–B, 50 D Street, Santa Rosa, CA. Requests for a copy of the draft MOU should be addressed to Chief, Protected Resources Division, NMFS, Southwest Region, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA, 90802–4213; or Supervisor, Northern California Protected Resources Division, NMFS, 777 Sonoma Avenue, Room 325, Santa Rosa, CA, 95404. Copies of the draft MOU may also be obtained by phone (see **FOR FURTHER INFORMATION CONTACT**). Written comments regarding the draft MOU should be directed to the same addresses.

**FOR FURTHER INFORMATION CONTACT:** Jim Lecky at (562) 980–4020, or Patrick Rutten at (707) 575–6059.

**SUPPLEMENTARY INFORMATION:**

## Background

The following information is furnished to provide a synopsis of NMFS' salmon and steelhead listing actions and critical habitat designation in California. This information frames the complexity and need for a Federal-State cooperative approach to salmonid management in California.

*A. Coho Salmon*

1. Central California coho Evolutionarily Significant Unit (ESU) listed as threatened on October 31, 1996 (61 FR 56138).

2. Southern Oregon/Northern California (SONC) coho listed as threatened on May 6, 1997 (62 FR 24588).

3. Endangered Species Act (ESA) 4(d) interim rule that applied the section 9 take prohibitions, with certain exceptions, to the SONC coho ESU was published by NMFS on July 18, 1997 (62 FR 38479), and became effective on August 18, 1997. The 60-day comment period on the interim final rule ended on September 16, 1997. NMFS will review all comments and publish a final rule in the **Federal Register** in the next 90 days.

4. NMFS is developing a proposed rule to designate critical habitat for the Central California and SONC coho salmon ESUs. The proposed rule is expected to publish in the **Federal Register** within the next 30 days.

*B. Steelhead*

1. On August 18, 1997 (62 FR 4393), NMFS listed the Southern California steelhead ESU as endangered and the Central California and South-Central California steelhead ESUs as threatened.

2. Section 9 take prohibitions were automatically applied to the endangered Southern California ESU at the time of listing.

3. NMFS is developing an ESA 4(d) interim rule that will apply the section 9 take prohibitions, with certain exceptions, to the Central California and South-Central California ESUs. An interim final rule is expected to publish in the **Federal Register** in the next 60 days.

4. At the time of the steelhead listing, NMFS announced that it was delaying its proposal for designating critical habitat. NMFS expects to designate critical habitat for these ESUs within the 1-year period allowed for in the ESA.

5. On August 18, 1997 (62 FR 43974), NMFS delayed its decision to list Central Valley, Northern California, and Klamath Mountains Province steelhead ESUs for 6 months. Accordingly, NMFS expects to publish in the **Federal Register** a final listing decision for these ESUs by February 18, 1998. If any of these steelhead ESUs are listed as threatened, NMFS will promulgate appropriate ESA 4(d) interim rules to apply the section 9 take prohibitions.

*C. Chinook Salmon*

1. NMFS is continuing work on its status review for West Coast chinook salmon.

2. In early 1997, NMFS provided copies of a draft status review for West Coast chinook to peer reviewers and its co-managers in California (i.e., California Department of Fish and Game, Indian tribes, and U.S. Fish and Wildlife Service) for review and comment. NMFS is reviewing these comments and gathering updated information for the status review.

3. NMFS expects to publish in the **Federal Register** a listing proposed rule for West Coast chinook salmon in early 1998.

## Watershed Restoration and Protection Council

The State, by Executive Order W–159–97, has established the WRPC to be responsible and provide oversight of State activities aimed at watershed protection and enhancement, including conservation and restoration of anadromous salmonids in California. The WRPC will be composed of State Secretaries and Chairs of Commissions, or Boards. The WRPC also establishes a Working Group whose members are Directors of State Agencies and Executive Officer's of Regional Water Quality Control Boards. An Executive Director of the WRPC will also be appointed and will be responsible for the coordination of the WRPC and Working Group.

NMFS in cooperation with the California Resources Agency is exploring entering into a MOU that will develop a process and mechanism, through the WRPC, that results in a State plan for the protection of the State's salmonid population. Completion and implementation of this State plan through the WRPC, in consultation with NMFS, will be the basis by which NMFS initiates a rulemaking action (pursuant to its authority under section 4(d) of the ESA) to adopt the State of California's plan or plans as equivalent to habitat conservation plans provided that NMFS determines that the plans are consistent with the requirements of the Federal ESA for issuing incidental take permits to non-Federal parties (section 10 of the ESA).

## Public Comments Solicited

The meeting will focus on the latest draft MOU provided to NMFS by the State of California. Participants are reminded that this is only a draft and that NMFS intends that the final MOU will take advantage of the information and recommendations from all interested parties. Therefore, comments and suggestions are hereby solicited from the public, other concerned governmental agencies, the scientific community, industry, and any other person concerned with these draft guidelines.

Dated: October 22, 1997.

**Hilda Diaz-Soltero,**

*Director, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 97–28441 Filed 10-27-97; 8:45 am]

BILLING CODE 3510–22–F

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## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

**[I.D. 102097B]**

## North Pacific Fishery Management Council; Public Meetings

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice of advisory group meetings scheduled in November, 1997.

**SUMMARY:** The North Pacific Fishery Management Council's (Council) Vessel Bycatch Accountability (VBA) Committee and Gulf of Alaska and Bering Sea/Aleutian Islands groundfish plan teams will hold meetings in November in Seattle, WA.

**DATES:** The VBA Committee will meet Friday, November 14, 1997, beginning at 8:00 a.m.

The groundfish plan teams will meet November 17–21, 1997, beginning at 1:00 p.m. on Monday, November 17.

**ADDRESSES:** VBA Committee: Nordby Conference Center, Suite A, Fishermen's Terminal, 1711 W. Nickerson, Seattle, WA.

Plan teams: Alaska Fisheries Science Center, 7600 Sand Point Way NE., Building 4, Room 2079, Seattle, WA.

*Council address*: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252.

**FOR FURTHER INFORMATION CONTACT:** Dave Witherell, telephone: 907–271–2809.

**SUPPLEMENTARY INFORMATION:**

1. The VBA Committee will further define options of a vessel bycatch accountability program, with emphasis on initial and annual allocations.

2. The groundfish plan teams will review any new stock assessment information and catch statistics, prepare final stock assessment documents for the 1998 groundfish fisheries in the Gulf of Alaska and Bering Sea/Aleutian Islands, and prepare recommendations for acceptable biological catches for individual species. The teams will also discuss streamlining the process of setting annual total allowable catches and review research needs and priorities.

Although other issues not contained in this agenda may come before the Committee or Plan Teams for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during the meetings. Committee or Plan Team action will be restricted to those issues specifically identified in the agenda listed in this notice.

## Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Helen Allen, 907–271–2809, at least 5 working days prior to the meeting date.

Dated: October 21, 1997.

**Richard W. Surdi,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 97–28443 Filed 10-27-97; 8:45 am]

**BILLING CODE 3510–22–F**

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## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

**[I.D. 101597C]**

## Western 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 Western Pacific Fishery Management Council (Council) and its committees will hold public meetings in Honolulu, HI. Prior to the Council meeting, the Council's Scientific and Statistical Committee (SSC) will hold its 67th meeting.

**DATES:** The meetings will be held on November 10–14, 1997. See **SUPPLEMENTARY INFORMATION** for specific dates and times.

**ADDRESSES:** The SSC meeting will be held at the Council office, 1164 Bishop Street, Suite 1400, Honolulu, HI; telephone: (808) 522–8220. The 94th Council meeting will be held at the Ala Moana Hotel, 410 Atkinson Dr., Garden Lanai and Hibiscus Ballroom, Honolulu, HI; telephone: (808) 955–4811.

*Council address*: Western Pacific Fishery Management Council, 1164 Bishop St., Suite 1400, Honolulu, HI 96813.

**FOR FURTHER INFORMATION CONTACT:** Kitty M. Simonds, Executive Director; telephone: (808) 522–8220.

**SUPPLEMENTARY INFORMATION:** The SSC meeting will be held on November 10–11, 1997, from 8:00 a.m. to 5:00 p.m., each day. The Council's Standing Committees will meet on November 12, 1997, as follows:

7:30 a.m. to 9:00 a.m.—Enforcement

8:00 a.m. to 10:00 a.m.—Crustaceans

9:00 a.m. to 10:30 a.m.—Vessel Monitoring System (VMS)

10:30 a.m. to 12:30 p.m.—Pelagics and Bottomfish

1:30 p.m. to 3:00 p.m.—Indigenous Fishing Rights and Ecosystem & Habitat

3:00 p.m. to 5:00 p.m.—Precious Corals and Executive/Budget & Programing

The full Council will meet on November 13–14, 1997, from 9:00 a.m. to 5:00 p.m., each day.

The SSC and Council will discuss and take final action on an amendment to establish a framework process for future management of precious corals (including public hearings). This will also be the first meeting under the framework procedure for pelagic fishery management changes for the American Samoa longline fishery regarding closed areas and a limited access program.

Other agenda items that the Council will discuss and may take action on include:

1. Pelagic fishery issues, including a) status of longline fisheries in Hawaii and American Samoa, b) international meetings addressing the management arrangements for highly migratory species, and c) protected species interaction/incidental take issues (turtles, sharks, albatross).

2. Bottomfish fishery issues, including a) status of the State's management plan focusing on monitoring and enforcement components, for overfished Main Hawaiian Islands (MHI) onaga and ehu, b) consideration of the Federal management alternatives for the recovery of overfished MHI onaga and ehu including a draft plan amendment, c) draft amendment for the limited access program for the Mau Zone in the Northwestern Hawaiian Islands (NWHI) including a public hearing, and d) update on armorhead fishery in the NWHI;

3. Crustacean fishery issues, including regulatory adjustments for 1998, such as allowing VMS carrying vessels to return directly back to port via the permit subzone, adding the month of May to the closed season of the main Hawaiian Islands lobster fishery within Federal waters, allowing vessels to temporarily leave fishing gear on the banks, opening the season one month earlier on 1 June, creating separate species and fishing bank quotas, providing fishermen with at least 24 hours notice before the close of the fishery, and announcing the harvest guideline 90 days after season closure;

4. Ecosystem and habitat issues, including a) consider the need for a coral reef fishery management plan, b) Essential Fish Habitat amendment and National Environmental Policy Act requirements, and c) Commonwealth of the Northern Mariana Islands Farallon de Mendinilla bombing issue;

5. Precious coral issues, including a) status of the fisheries, and b) consistency between state and Federal regulations;

6. Native rights and indigenous fishing issues, including the status of Demonstration Projects and Community Development Programs;

7. Enforcement and VMS issues, including a) reports from the U.S. Coast Guard and NMFS Enforcement, b) status of violations, and c) possible changes to the Council's VMS policy;

8. Program planning and administrative issues, including a) Council milestones for 2000–2003, b) Standard Operating Practices and Procedure revision, c) election of officers, and d) meetings and workshops; and

9. Other business as required.

Although other issues not contained in this agenda may come before this Council for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal Council action during this meeting. Council action will be restricted to those issues specifically identified in the agenda listed in this notice.

### Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to meeting date.

Dated: October 21, 1997.

**Richard W. Surdi,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 97–28442 Filed 10-27-97; 8:45 am]

BILLING CODE 3510–22–F

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## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

**[102197B]**

## Marine Mammals; Permit No. 837 (P77–1#67)

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Scientific research permit amendment.

**SUMMARY:** Notice is hereby given that a request for amendment of scientific research permit no. 837 submitted by The National Marine Mammal Laboratory, Alaska Fisheries Science Center, NMFS, NOAA, 7600 Sand Point Way NE., BIN C15700, Seattle, Washington 98115, has been granted.

**ADDRESSES:** The amendment and related documents are available for review upon written request or by appointment in the following office(s):

Permits and Documentation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (301/713–2289); and

Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802–1668.

**SUPPLEMENTARY INFORMATION:** On September 12, 1997, notice was published in the **Federal Register** (62 FR 48062) that an amendment of permit no. 837, issued June 4, 1993 (58 FR 33085), had been requested by the above-named organization. The original permit authorized studies on northern fur seals (*Callorhinus ursinus*) over a five-year period on rookeries in the Bering Sea and eastern North Pacific Ocean. The requested amendment has been granted under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the provisions of § 216.39 of the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

The permit was amended to authorize the following increased takings of northern fur seals (*Callorhinus ursinus*): To collect biopsy samples from 30 additional females on St. Paul and 30 additional females on St. George Islands. The total number of females to be biopsy sampled on both St. Paul and St. George will increase to 180 (90 on each island).

Dated: October 20, 1997.

**Ann Terbush,**

*Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 97–28439 Filed 10-27-97; 8:45 am]

BILLING CODE 3510–22–F

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## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

**[I.D.092697B]**

## Marine Mammals; Scientific Research Permit No. 1016 (P167H)

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Receipt of application for amendment.

**SUMMARY:** Notice is hereby given that Ann E. Bowles, Ph.D., Senior Research Biologist, Hubbs-Sea World Research Institute, 2595 Ingraham Street, San Diego, California 92109, has requested an amendment to Permit No. 1016.

**DATES:** Written comments must be received on or before November 27, 1997.

**ADDRESSES:** The application and related documents are available for review upon written request or by appointment in the following office(s):

Permits Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (301/713-2289); and

Regional Administrator, Southwest Region, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802-4213 (310/980-4001).

Written data or views, or requests for a public hearing on this request, should be submitted to the Director, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this application would be appropriate.

Concurrent with the publication of this notice in the Federal Register, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

**SUPPLEMENTARY INFORMATION:** The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 et seq.) and the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216).

Permit No. 1016 authorizes the permittee to harass several species of stranded rehabilitated and permanently captive pinnipeds and small cetaceans in order to measure their interaction with fishing gear and to determine the effect of introducing an auditory stimulus (i.e., pinger) on responses. The research is authorized to be conducted over a five year period. The permittee is now requesting to: add 2 pinger trials and 2 net trials with 14 of the 18 California sea lions (*Zalophus californianus*) currently authorized to be involved in motivational state trials; and increase the number of California sea lions to be used in the naive trials from 30 to 40.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: September 26, 1997.

**Ann D. Terbush,**

*Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 97–28444 Filed 10-27-97; 8:45 am]

BILLING CODE 3510–22–F

## COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

### Adjustment of Import Limits for Certain Cotton, Wool and Man-Made Fiber Textiles and Textile Products and Silk Blend and Other Vegetable Fiber Apparel Produced or Manufactured in the Philippines

October 22, 1997.

**AGENCY:** Committee for the Implementation of Textile Agreements (CITA).

**ACTION:** Issuing a directive to the Commissioner of Customs adjusting import limits.

**EFFECTIVE DATE:** October 30, 1997.

**FOR FURTHER INFORMATION CONTACT:** Janet Heinzen, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–5850. For information on embargoes and quota re-openings, call (202) 482–3715.

**SUPPLEMENTARY INFORMATION:**

**Authority:** Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Uruguay Round Agreements Act.

The current limits for certain categories are being adjusted for special shift.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 61 FR 66263, published on December 17, 1996). Also see 61 FR 64507, published on December 5, 1996.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles, but are designed to assist only in the implementation of certain of their provisions.

**Troy H. Cribb,**

*Chairman, Committee for the Implementation of Textile Agreements.*

**Committee for the Implementation of Textile Agreements**

October 22, 1997.

Commissioner of Customs,

*Department of the Treasury, Washington, DC 20229.*

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on November 29, 1996, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool and man-made fiber textiles and textile products and silk blend and other vegetable fiber apparel, produced or manufactured in the Philippines and exported during the twelve-month period beginning on January 1, 1997 and extending through December 31, 1997.

Effective on October 30, 1997, you are directed to adjust the current limits for the following categories, pursuant to the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing:

| Category | Adjusted twelve-month limit [1] |
|---|---|
| Levels in Group I | |
| 237 | 727,157 dozen. |
| 338/339 | 2,208,953 dozen. |
| 638/639 | 2,535,437 dozen. |
| Group II | |
| 200–229, 300–326, 330, 332, 349, 353, 354, 359–O [2], 360, 362, 363, 369–O [3], 400–414, 432, 434–442, 444, 448, 459, 464–469, 600–607, 613–629, 630, 632, 644, 653, 654, 659–O [4], 665, 666, 669–O [5], 670–O [6], 831–846 and 850–859, as a group. | 171,119,294 square meters equivalent. |

[1] The limits have not been adjusted to account for any imports exported after December 31, 1996.

[2] Category 359–O: all HTS numbers except 6103.42.2025, 6103.49.8034, 6104.62.1020, 6104.69.8010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010 (Category 359–C).

[3] Category 369–O: all HTS numbers except 6307.10.2005 (Category 369–S).

[4] Category 659–O: all HTS numbers except 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.8038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.8014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.9010, 6211.33.0010, 6211.33.0017, 6211.43.0010 (Category 659–C); 6502.00.9030, 6504.00.9015, 6504.00.9060, 6505.90.5090, 6505.90.6090, 6505.90.7090 and 6505.90.8090 (Category 659–H).

[5] Category 669–O: all HTS numbers except 6305.32.0010, 6305.32.0020, 6305.33.0010, 6305.33.0020 and 6305.39.0000 (Category 669–P).

[6] Category 670–O: all HTS numbers except 4202.12.8030, 4202.12.8070, 4202.92.3020, 4202.92.3030 and 4202.92.9025 (Category 670–L).

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Troy H. Cribb,

*Chairman, Committee for the Implementation of Textile Agreements.*

[FR Doc. 97–28501 Filed 10–27–97; 8:45 am]

BILLING CODE 3510–DR–F

## DEPARTMENT OF DEFENSE

## GENERAL SERVICES ADMINISTRATION

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

**[OMB Control No. 9000–0134]**

### Proposed Collection; Comment Request Entitled Environmentally Sound Products

**AGENCIES:** Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

**ACTION:** Notice of request for public comments regarding an extension to an existing OMB clearance.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning Environmentally Sound Products. The clearance currently expires on February 28, 1998.

**DATES:** Comments may be submitted on or before December 29, 1997.

**FOR FURTHER INFORMATION CONTACT:** Ralph DeStefano, Federal Acquisition Policy Division, GSA (202) 501–1758.

**ADDRESSES:** Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, should be submitted to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, FAR Secretariat, 1800 F Street, NW, Room 4037, Washington, DC 20405. Please cite OMB Control No. 9000–0134,

Environmentally Sound Products, in all correspondence.

**SUPPLEMENTARY INFORMATION:**

## A. Purpose

This information collection complies with Section 6002 of the Resource Conservation and Recovery Act (RCRA) (42 U.S.C. 6962). RCRA requires the Environmental Protection Agency (EPA) to designate items which are or can be produced with recovered materials. RCRA further requires agencies to develop affirmative procurement programs to ensure that items composed of recovered materials will be purchased to the maximum extent practicable. Affirmative procurement programs required under RCRA must contain, as a minimum (1) a recovered materials preference program and an agency promotion program for the preference program; (2) a program for requiring estimates of the total percentage of recovered materials used in the performance of a contract, certification of minimum recovered material content actually used, where appropriate, and reasonable verification procedures for estimates and certifications; and (3) annual review and monitoring of the effectiveness of an agency's affirmative procurement program.

The items for which EPA has designated minimum recovered material content standards are (1) cement and concrete containing fly ash, (2) paper and paper products, (3) lubricating oil containing re-refined oil, (4) retread tires, and (5) building insulation products. The FAR rule also permits agencies to obtain pre-award information from offerors regarding the content of items which the agency has designated as requiring minimum percentages of recovered materials. There are presently no known agency designated items.

In accordance with RCRA, the information collection applies to acquisitions requiring minimum percentages of recovered materials, when the price of the item exceeds $10,000 or when the aggregate amount paid for the item or functionally equivalent items in the preceding fiscal year was $10,000 or more.

Contracting officers use the information to verify offeror/contractor compliance with solicitation and contract requirements regarding the use of recovered materials. Additionally, agencies use the information in the annual review and monitoring of the effectiveness of the affirmative procurement programs required by RCRA.

## B. Annual Reporting Burden

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows: Respondents, *64,350*; responses per respondent, *1*; total annual responses, *64,350*; preparation hours per response, *.5*; and total response burden hours, *32,175*.

*Obtaining Copies of Proposals:* Requester may obtain a copy of the justification from the General Services Administration, FAR Secretariat (MVRS), Room 4037, 1800 F Street, NW, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB control No. 9000–0134, Environmentally Sound Products, in all correspondence.

Dated: October 20, 1997.

**Sharon A. Kiser,**

*FAR Secretariat.*

[FR Doc. 97–28479 Filed 10–27–97; 8:45 am]

BILLING CODE 6820–34–P

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# DEPARTMENT OF EDUCATION

## Notice of Proposed Information Collection Requests

**AGENCY:** Department of Education.

**ACTION:** Notice of Proposed Information Collection Requests.

**SUMMARY:** The Deputy Chief Information Officer, Office of the Chief Information Officer, 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 November 10, 1997. A regular clearance process is also beginning. Interested persons are invited to submit comments on or before December 29, 1997.

**ADDRESSES:** Written comments regarding the emergency review should be addressed to the Office of Information and Regulatory Affairs, Attention: Dan Chenok, Desk Officer: Department of Education, Office of Management and Budget, 725 17th Street, NW., 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, DC 20202–4651, or should be electronic 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 Deputy Chief Information Officer, Office of the Chief Information Officer, 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 22, 1997.

**Gloria Parker,**

*Deputy Chief Information Officer, Office of the Chief Information Officer.*

**Office of Vocational and Adult Education.**

*Type of Review:* Extension.

*Title:* Performance Report for State-Administered Vocational Technical Education Programs

*Abstract:* This report will identify students served in the state vocational-technical system with emphasis on special populations, indicate those states in need of technical assistance to improve services to those students, and provide trend data to demonstrate the effectiveness of vocational-technical education in meeting the needs of youth and adults.

*Additional Information:* This information request represents an extension of a collection previously approved by OMB . It is being submitted at this time because as recently as August of this year we had been anticipating the passage of new legislation for vocational-technical education and had been crafting new directions for States to follow that would be oriented toward the accountability requirements of the new law as well as the requirements of the Results Act. The House Representatives passed its version of new legislation in June and the Senate was anticipating action by early September. It now appears that enactment of a new Federal law for vocational-technical education will not occur until 1998 and will likely have an implementation date of July 1999.

*Frequency:* Annually.

*Affected Public:* State, local or Tribal Gov't, SEAs or LEAs.

*Reporting and Recordkeeping Burden:*

Responses: 53.

Burden Hours: 2,756.

[FR Doc. 97–28468 Filed 10–27–97; 8:45 am]

BILLING CODE 4000–01–P

## DEPARTMENT OF ENERGY

### Office of Arms Control and Nonproliferation Policy; Proposed Subsequent Arrangement

**AGENCY:** Department of Energy.

**ACTION:** Subsequent Arrangement.

**SUMMARY:** Pursuant to section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160), notice is hereby given of a proposed ''subsequent arrangement'' under the Agreement for Cooperation in the Peaceful Uses of Nuclear Energy Between the United States of America and the European Atomic Energy Community (EURATOM) and the Agreement for Cooperation Between the Government of the United States of America and the Government of Canada Concerning the Civil Uses of Atomic Energy.

The subsequent arrangement to be carried out under the above-mentioned agreements involves approval of the following: RTD/EU(CA)–14 for the transfer of 15,000 grams of enriched uranium fuel fabrication scrap, containing 2,962.5 grams of the isotope $U^{235}$ (less than 20 percent enrichment) from AECL in Chalk River, Canada, to UKAEA in Dounreay, United Kingdom, for the purpose of recovering uranium for return to Canada in the form of uranium metal pieces to be used in the fabrication of NRU reactor fuel.

In accordance with section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen days after the date of publication of this notice.

Dated: October 22, 1997.

For the Department of Energy.

**Cherie P. Fitzgerald,**

*Director, International Policy and Analysis Division, Office of Arms Control and Nonproliferation.*

[FR Doc. 97–28509 Filed 10–27–97; 8:45 am]

BILLING CODE 6450–01–P

## DEPARTMENT OF ENERGY

### Office of Arms Control and Nonproliferation Policy; Proposed Subsequent Arrangement

**AGENCY:** Department of Energy.

**ACTION:** Subsequent Arrangement.

**SUMMARY:** Pursuant to section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160), notice is hereby given of a proposed ''subsequent arrangement'' under the Agreement for Cooperation in the Peaceful Uses of Nuclear Energy Between the United States of America and the European Atomic Energy Community (EURATOM) and the Agreement for Cooperation Between the Government of the United States of America and the Government of Canada Concerning the Civil Uses of Atomic Energy.

The subsequent arrangement to be carried out under the above-mentioned agreements involves approval of the following: RTD/EU(CA)–15 for the transfer of 25,000 grams of enriched uranium fuel fabrication scrap, containing 23,280 grams of the isotope U–235 (93.15 percent enrichment) from AECL in Chalk River, Canada, to UKAEA in Dounreay, United Kingdom, for the purpose of recovering high enriched uranium for return to Canada within a twelve month period for use as target material for the production of Molybdenum 99.

In accordance with section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen days after the date of publication of this notice.

For the Department of Energy.

Dated: October 22, 1997.

**Cherie P. Fitzgerald,**

*Director, International Policy and Analysis Division, Office of Arms Control and Nonproliferation.*

[FR Doc. 97–28510 Filed 10–27–97; 8:45 am]

BILLING CODE 6450–01–P

## DEPARTMENT OF ENERGY

### American Statistical Association Committee on Energy Statistics; Notice of Open Meeting

**AGENCY:** Department of Energy.

**SUMMARY:** Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. No. 92–463, 86 Stat. 770), notice is hereby given of the following meeting:

**NAME:** American Statistical Association Committee on Energy Statistics.

**DATES AND TIMES:** Thursday, November 13, 9:00 am–5:00 pm. Friday, November 14, 9:00 am–12:00 noon.

**ADDRESSES:** Holiday Inn-Capitol, 550 C Street, S.W., Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Mr. William I. Weinig, EIA Committee Liaison, U.S. Department of Energy, Energy Information Administration, EI–70, Washington, DC 20585, Telephone: (202) 426–1101.

**SUPPLEMENTARY INFORMATION:**

**Purpose of Committee**

To advise the Department of Energy, Energy Information Administration

(EIA), on EIA technical statistical issues and to enable the EIA to benefit from the Committee's expertise concerning other energy statistical matters.

*Tentative Agenda*

Thursday, November 13, 1997

A. Opening Remarks
B. Major Topics
1. Electricity Today: A Briefing
2. Electricity Prices in a Competative Environment
3. Petroleum Marketing Disclosure Avoidance Techniques
4. Electricity Auctions Under the Concept of ''Open Transmission Access'' *
5. A Prototype Network Model of the New England Power Pool
6. Public Comment

* To be conducted in the Forrestal Building at 1000 Independence Ave., S.W., Washington, D.C., Room GI–034(A).

Friday, November 14, 1997

1. Use of Covariates to Improve Efficiency of Estimation
2. Estimated Supply Functions on International Crude Oil for 41 Countries: A Model
3. Public Comment
4. Closing Comments by the Chairperson

**Public Participation**

The meeting is open to the public. The Chairperson of the committee is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Written statements may be filed with the committee either before or after the meeting. If there are any questions, please contact Mr. William Weinig, EIA Committee Liaison, at the address or telephone number listed above.

**Minutes and Transcripts**

Available for public review and copying at the Public Reading Room, (Room 1E–190), 1000 Independence Avenue, SW, Washington, DC 20585, (202) 586–3142, between the hours of 9:00 a.m. and 4:00 p.m., Monday through Friday.

Issued at Washington, DC on October 22, 1997.

**Rachel M. Samuel,**

*Deputy Advisory Committee Management Officer.*

[FR Doc. 97–28507 Filed 10–27–97; 8:45 am]

BILLING CODE 6450–01–P

## DEPARTMENT OF ENERGY

### Environmental Management Site-Specific Advisory Board, Fernald

**AGENCY:** Department of Energy.

**ACTION:** Notice of open meeting.

**SUMMARY:** Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) notice is hereby given of the following Advisory Committee meeting: Environmental Management Site-Specific Advisory Board (EM SSAB), Fernald.

**DATES:** Saturday, November 15, 1997—8:30 a.m.–12 p.m.; (public comment session: 11:45 a.m.–12 p.m.)

**ADDRESSES:** Alpha Building, 10967 Hamilton-Cleves Highway, Harrison, Ohio.

**FOR FURTHER INFORMATION CONTACT:** John S. Applegate, Chair of the Fernald Citizens Task Force, PO Box 544, Ross, Ohio 45061, or call the Fernald Citizens Task Force office (513) 648–6478.

**SUPPLEMENTARY INFORMATION:** Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of future use, cleanup levels, waste disposition and cleanup priorities at the Fernald site.

**Tentative Agenda**

8:30 a.m.—Call to Order
8:30–8:40—Opening Remarks
8:40–9:00—Committee Reports
9:00–9:15—Review of Site Tour
9:15–10:15—Prioritization and Long-Term Planning
10:15–10:30—Break
10:30–11:45—Overhead Cost Reduction
11:45–12:00—Opportunity for Public Input
12:00 p.m.—Adjourn

A final agenda will be available at the meeting, Saturday, November 15, 1997.

**Public Participation**

The meeting is open to the public. Written statements may be filed with the Board chair either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact the Board chair at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Official, Gary Stegner, Public Affairs Officer, Ohio Field Office, U.S. Department of Energy, is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments.

**Minutes**

The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585 between 9 a.m. and 4 p.m., Monday–Friday, except Federal holidays. Minutes will also be available by writing to John S. Applegate, Chair, the Fernald Citizens Task Force, PO Box 544, Ross, Ohio 45061 or by calling the Task Force message line at (513) 648–6478.

Issued at Washington, DC on October 22, 1997.

**Rachel Samuel,**

*Deputy Advisory Committee Management Officer.*

[FR Doc. 97–28505 Filed 10–27–97; 8:45 am]

BILLING CODE 6450–01–P

## DEPARTMENT OF ENERGY

### Environmental Management Site-Specific Advisory Board, Paducah

**AGENCY:** Department of Energy.

**ACTION:** Notice of Open Meeting.

**SUMMARY:** Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) notice is hereby given of the following Advisory Committee meeting: Environmental Management Site-Specific Advisory Board (EM SSAB), Paducah Gaseous Diffusion Plant.

**DATES:** Thursday, November 20, 1997: 6:00 p.m.–9:00 p.m.

**ADDRESSES:** Heath High School (cafeteria), 4330 Metropolis Lake Road, West Paducah, Kentucky.

**FOR FURTHER INFORMATION CONTACT:** Carlos Alvarado, Site-Specific Advisory Board Coordinator, Department of Energy Paducah Site Office, Post Office Box 1410, MS–103, Paducah, Kentucky 42001, (502) 441–6804.

**SUPPLEMENTARY INFORMATION:**

*Purpose of the Board:* The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

*Tentative Agenda:* The meeting will include updates on the Environmental Management and Enrichment Facilities Project, Waste Management, and Effective & Meaningful Public Input reports; administrative plans; and an Environmental Management Evaluation Ranking Matrix. It will also include a drum update; a review of the SSAB Draft Work Plan; a media contact discussion; and an update on Waste Area Grouping 22.

*Public Participation:* The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals

who wish to make oral statements pertaining to agenda items should contact Carlos Alvarado at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Official is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments as the first item on the meeting agenda.

*Minutes:* The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585 between 9:00 a.m. and 4 p.m., Monday-Friday, except Federal holidays. Minutes will also be available at the Department of Energy's Environmental Information and Reading Room at 175 Freedom Boulevard, Highway 60, Kevil, Kentucky between 8:00 a.m. and 5:00 p.m. on Monday through Friday, or by writing to Carlos Alvarado, Department of Energy Paducah Site Office, Post Office Box 1410, MS–103, Paducah, Kentucky 42001, or by calling him at (502) 441–6804.

Issued at Washington, DC on October 22, 1997.

**Rachel Samuel,**

*Deputy Advisory Committee Management Officer.*

[FR Doc. 97–28506 Filed 10–27–97; 8:45 am]

BILLING CODE 6450–01–P

## DEPARTMENT OF ENERGY

### Environmental Management Site-Specific Advisory Board, Oak Ridge Reservation

**AGENCY:** Department of Energy.

**ACTION:** Correction.

**SUMMARY:** In notice document FR 97–27285 beginning on page 53606 in the issue of Wednesday, October 15, 1997, make the following correction:

On page 53606 in the third column, the DATE of the meeting was incorrectly listed as October 5, 1997. This should be changed to read November 5, 1997.

Issued at Washington, DC on October 22, 1997.

**Rachel Samuel,**

*Deputy Advisory Committee Management Officer.*

[FR Doc. 97–28508 Filed 10–27–97; 8:45 am]

BILLING CODE 6450–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER97–4410–000]**

### Detroit Edison Company; Notice of Filing

October 16, 1997.

Take notice that on September 24, 1997, Detroit Edison Company tendered for filing an amendment in the above-referenced docket.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before October 28, 1997. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–28538 Filed 10–27–97; 8:45 am]

BILLING CODE 6717–01–M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. RP98–18–000]**

### Iroquois Gas Transmission System L.P.; Notice of Proposed Changes in FERC Gas Tariff

October 22, 1997.

Take notice that on October 17, 1997, Iroquois Gas Transmission System, L.P. (Iroquois), tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the tariff sheets listed on the filing, with an effective date of November 16, 1997.

Iroquois states that the primary purpose of filing these sheets is to revise Iroquois' tariff to permit Iroquois and shippers receiving service under its RTS and ITS Rate Schedule to agree to negotiated rates for its transportation services. This program is designed to be consistent with the Commission's Statement of Policy, Alternatives to Traditional Cost-of-Service Ratemaking for Natural Gas Pipelines, 74 FERC ¶61,076 (1996). In addition, Iroquois states that it has made several other minor tariff changes to correct typos or other errors, to update its Service Request Form, and to add a new Blanket Capacity Release Form and Blanket Capacity Release Fact Sheet.

Iroquois states that copies of this filing were served upon all customers and interested state regulatory agencies.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make Protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–28464 Filed 10–27–97; 8:45 am]

BILLING CODE 6717–01–M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. MG96–13–005]**

### K N Interstate Gas Transmission Company; Notice of Filing

October 22, 1997.

Take notice that on October 14, 1997, K N Interstate Gas Transmission Company (KNI) submitted revised standards of conduct in response to the Commission's August 6, 1997, order.[1]

KNI states that copies of this filing have been mailed to all parties on the official service list compiled by the Secretary in this proceeding. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C., 20426, in accordance with Rules 211 or 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214). All such motions to intervene or protest should be filed on or before November 6, 1997. Protests

[1] 80 FERC ¶ 61,212 (1997).

will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–28460 Filed 10–27–97; 8:45 am]

BILLING CODE 6717–01–M

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## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Docket No. MG96–14–002]**

## K N Wattenberg Transmission Limited Liability Company; Notice of Filing

October 22, 1997.

Take notice that on October 14, 1997, K N Wattenberg Limited Liability Company (KNW) submitted revised standards of conduct in response to the Commission's September 15, 1997, order.[1]

KNW states that copies of this filing have been mailed to all parties on the official service list compiled by the Secretary in this proceeding. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C., 20426, in accordance with Rules 211 or 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214). All such motions to intervene or protest should be filed on or before November 6, 1997. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–28461 Filed 10–27–97; 8:45 am]

BILLING CODE 6717–01–M

[1] 80 FERC ¶ 61,291 (1997).

## DEPARTMENT OF ENERGY

**[Docket No. ER97–4799–000]**

## Maine Public Service Company; Notice of Filing

October 22, 1997.

Take notice that on September 30, 1997, Maine Public Service Company filed an executed Service Agreement with PacifiCorp Marketing, Inc.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before November 3, 1997. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–28458 Filed 10–27–97; 8:45 am]

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## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Docket No. EL95–3–001]**

## MidAmericna Energy Company (formerly Midwest Power Systems Inc.; Order Granting Intervention and Denying Rehearing

Issued October 22, 1997.

Before Commissioners: James J. Hoecker, Chairman; Vicky A. Bailey, and William L. Massey.

On June 13, 1997, Southern Company Services, Inc. (Southern)[1] filed a motion to intervene out of time and a request for rehearing of the Commission's order issued May 15, 1997. *MidAmerican Energy Company (formerly Midwest Power Systems, Inc.),* 79 FERC ¶ 61,169 (1997) (May 15 order). For the reasons stated below, we will grant the motion to intervene and deny the rehearing request.

### Background

In the May 15 order, the Commission: (a) dismissed as moot a request by Midwest Power, a division of Midwest Power Systems Inc. (Midwest Power or Applicant),[2] for a declaratory order authorizing it to reduce its annual composite rate of depreciation for accounting purposes;[3] and (b) clarified its order, issued April 19, 1994, in *Midwest Power Systems Inc.*, 67 FERC ¶ 61,076 (1994) (*Midwest Power*), which noted that section 302(a) of the FPA, 16 U.S.C. § 825a(a) (1994), requires that public utilities and licensees filed for Commission approval of proposed depreciation rate changes for accounting purposes. The Commission noted that, notwithstanding the clear language of section 302(a), there apparently was some confusion in the industry as to what should be done. Accordingly, the Commission did not require public utilities and licensees to file for formal approval of depreciation rate changes for accounting purposes where the depreciation rate changes were based on sound depreciation accounting practices and implemented prior to April 19, 1994. For changes in depreciation rates for accounting purposes implemented on or after April 19, 1994, and prior to the date of publication of the May 15 order in the **Federal Register**,[4] the Commission accorded public utilities and licensees an amnesty period extending to and including December 31, 1997, to make filings to change their depreciation rates for accounting purposes.[5]

### Southern's Rehearing Request

Southern has moved to intervene out of time in order to seek rehearing of the

[1] Southern states that it is acting as agent for Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company, and Savannah Electric and Power Company (collectively referred to as the Southern Companies).

[2] By order issued June 22, 1995, the Commission authorized the merger of Midwest Power and Iowa-Illinois Gas and Electric Company. MidAmerican Energy Company is the surviving corporation. *See* Midwest Power Systems, Inc. and Iowa-Illinois Gas and Electric Company, 71 FERC ¶ 61,386 (1995).

[3] Midwest Power did not make this proposal in the context of a ratemaking proceeding under sections 205 or 206 of the Federal Power Act (FPA). 16 U.S.C. §§ 824d, e (1994). Accordingly, this order addresses only changes in depreciation rates for accounting purposes, and not recovery of depreciation-related expenses in, or changes in, electric rates and charges. Likewise, this order does not address requests to change depreciation rates that are made as part of proposals to change electric rates and charges under sections 205 or 206 of the EPA.

[4] The order was published in the Federal Register on May 22, 1997.

[5] The Commission also clarified that requests for depreciation rate changes for accounting purposes may be made under Rule 204 of the commission's Rules of Practice and Procedure, 18 CFR § 385.204 (1996), which does not require payment of a filing fee.

May 15 order. Southern argues that section 302 is an enabling statute and is not self-executing. Thus, Southern maintains, section 302 does not require public utilities and licensees to seek Commission authorization. Rather, while section 302 authorizes the Commission to fix depreciation rates, the Commission may do so only if the Commission first holds a hearing and provides prior notice to the affected state commissions.

Southern argues that there is no evidence in the legislative history that congress intended section 302 to impose an affirmative obligation on public utilities and licensees to obtain formal pre-approval of depreciation rates; rather, the Commission must comply with the preconditions of section 302(b) (*i.e.*, to receive and consider the views of state commissions before prescribing any rules or requirements as to depreciation rates).

Southern next argues that the Commission has never interpreted section 302 to impose an affirmative obligation on public utilities and licensees to secure formal Commission pre-approval for all depreciation rate changes, but has either avoided the issue, citing *Arkansas Power & Light Co.*, 8 FPC 106 (1949) (*AP&L*),[6] or held that section 205 of the FPA could be used as the procedural vehicle to set depreciation rates, citing *Carolina Power & Light Co.*, 55 FPC 817 (1976) (*CP&L*).[7] Southern adds that there is little judicial precedent regarding interpretation of section 302.[8] Southern argues that because the May 15 order departs from past precedent without a reasoned explanation, it is arbitrary and capricious.[9]

Southern claims that the Commission violated the Administrative Procedure Act (APA)[10] by failing to provide for prior notice and comment before issuing the May 15 order, which it characterizes as rulemaking. Further, Southern contends that any ''rule'' the Commission might promulgate can only be applied prospectively, and argues that the Commission erred in applying the ''rule'' announced in the May 15 order retroactively to the date of the *Midwest Power* decision.

Southern next argues that while the May 15 order provides for notification to state commissions, this notification does not satisfy the requirements of section 302 because the states and interested parties were not accorded an opportunity to have their views heard *before* Commission announced its policy.[11] Southern maintains that the Commission's decision in *Prior Notice and Filing Requirements Under Part II of the Federal Power Act*, 64 FERC ¶ 61,138, *order on reh'g*, 65 FERC ¶ 61,081 (1993) (*Prior Notice*), confirms that the Commission should have provided prior notice and allowed for the filing of comments and participation by affected parties.[12] Southern also argues that the May 15 order violates its due process rights because Southern was not allowed to challenge the Commission's requirements set forth in that order.[13] Further, Southern argues that to the extent the May 15 order establishes an amnesty period to submit proposed depreciation rate changes, it again violates the requirements of section 302, the APA, and considerations of due process.[14]

Southern also argues that the May 15 order imposes unnecessary regulations and filing requirements, which are inconsistent with ongoing changes in the electric utility industry. Southern notes the increasing use of market-based rates by public utilities and power marketers. It submits that entities selling at market-based rates do not predicate their charges on their depreciation expenses or any other identified cost components. Southern also notes the availability of section 205 and 206 proceedings to establish and monitor depreciation rates.

Finally, Southern notes that the overwhelming majority of plant and equipment affected by the May 15 order is used to provide retail electric service under state jurisdiction. It argues that if the Commission imposes a preapproval policy, public utilities could be subjected to incompatible regulatory requirements, with the Commission requiring one depreciation rate to be reflected in the utilities' books of account while a state commission could require a different depreciation rate. It maintains that the Commission should only regulate the depreciation accounting practices of jurisdictional public utilities to the extent the

[6] Southern states that in *AP&L*, 8 FPC at 121, the company had argued that this Commission could only require adjustments to the depreciation reserve in a proceeding under section 302(a), and inasmuch as this Commission had issued no rules or regulations under section 302(a), the prior action of the Arkansas Commission (authorizing the contested accounting entry) was controlling. Southern argues that, instead of responding to this argument, this Commission brushed it aside by clarifying that it was acting under section 301(a) of the FPA, 16 U.S.C. § 825(a) (1994), and not section 302.

[7] Southern notes that in *CP&L*, 55 FPC at 819, the Commission stated:

With respect to the issue of CP&L's increased depreciation rates reflected in its filing both [intervenors] contend that Section 302 of the Federal Power Act requires that an increase in depreciation must be approved *prior to* the time it may be reflected in a company's rate filing and that the rate may only be permitted to be utilized prospectively from the Commission's finding. It is our view that the intervenor's reading of Section 302 of the Federal Power Act is too restrictive. Nothing in that section prevents rates utilizing an increased depreciation rate from being permitted to become effective subject to refund.

(emphasis in original).

[8] *Citing* Jersey Central Power & Light Co. v. FPC, 129 F.2d 183, 189 n.2 (3d Cir. 1942) (finding that the court had jurisdiction to review the Commission's determination that Jersey Central is a public utility within the meaning of the Federal Power Act, and reciting the applicable statutory provisions, including sections 301 and 302); Hartford Electric Light Co. v. FPC, 131 F.2d 953, 963 n.20 (2d Cir. 1942) (in which the court observed that since petitioner is a public utility subject to the Commission's jurisdiction, the Commission would have authority to fix depreciation rates under section 302); Safe Harbor Water Power Corp v. FPC, 179 F.2d 179, 199 (3d Cir. 1949) (in which the court approved the Commission's finding that a straight-line depreciation method is proper under section 302); and Union Electric Co. v. FPC, 326 F.2d 535, 539 n.1 (8th Cir. 1964), *rev'd on other grounds*, 381 U.S. 90 (1965) (stating that the Commission may fix rates of depreciation and may prescribe what charges are to be treated as depreciation charges).

[9] We note that, contrary to Southern's claim, the Commission in its prior orders has never held that under section 302 of the FPA public utilities and licensees were *not* required to file for approval of changes in their depreciation rates for accounting purposes with the Commission. The Commission has also never stated that they could change their depreciation rates for accounting purposes unilaterally *without* a filing with the Commission.

[10] 5 U.S.C. §§ 551 *et seq.* (1994).

[11] While we, in fact, did provide for the May 15 order to be sent to all of the state commissions, and also published in the **Federal Register**, *see* 79 FERC at 61,795; 62 Fed. Reg. 28,105 (1997), not a single state commission has responded or otherwise indicated any objection to or disagreement with the order.

[12] The *Prior Notice* proceeding is distinguishable, as it involved questions of what agreements were jurisdictional in the first instance and therefore needed to be filed. *See Prior Notice*, 64 FERC at 61,973, 61,977–78, 61,984–96. Here, in contrast, as discussed below, the need for public utilities and licensees to file for Commission authorization to change their depreciation rates for accounting purposes is plain on the face of the statute.

[13] In this regard, however, we note that Southern has had an opportunity here, on rehearing, to make its case. *See, e.g.*, Accounting Release AR–14, 58 FERC ¶ 61,166 at 61,501 & n.45 (1992). Moreover, we have not, in this proceeding, acted on any proposed depreciation rate change of Southern; rather, we have instead simply reiterated the need for public utilities and licensees to file with this Commission as required by section 302 of the FPA.

When public utilities and licenses make filings seeking to change their depreciation rates for accounting purposes, our practice is to publish notice of such filings in the **Federal Register**. In fact, notice of Midwest Power's filing in this proceeding (*i.e.*, its petition for a declaratory order) was published in the **Federal Register**. *See* 79 FERC at 61, 794; 59 Fed. Reg. 55,472 (1994).

[14] The amnesty period we provided for in the May 15 order was simply an accommodation to the industry to allow them the opportunity to make filings that would be considered timely. The Commission was not required to provide such an amnesty period, but chose to do so; the Commission's interest is in ensuring that public utilities and licensees comply with the statute's requirements, and the Commission believed that an amnesty period would further that policy.

underlying capital is dedicated to jurisdictional, cost-based service.

**Discussion**

Southern's motion to intervene out of time is unopposed, and Southern's interests may be affected by the outcome of this proceeding and cannot be represented by any other party. Nor would granting intervention result in undue prejudice. In these circumstances, we find good cause to grant Southern's motion to intervene out of time.

We will deny Southern's rehearing request. Contrary to Southern's position, pursuant to the express language of section 302 of the FPA public utilities and licensees must obtain Commission approval for changes in depreciation rates for accounting purposes.

Section 301(a) of the FPA, 16 U.S.C. § 825(a) (1994), in the first instance empowers the Commission to require utilities to keep ''accounts, records of cost-accounting procedures, correspondence, memoranda, papers, books and other records as the Commission may by rules and regulations prescribe as necessary or appropriate for purposes of the administration of this Act * * *.'' [15] Section 302(a) of the FPA, 16 U.S.C. § 825a(a) (1994), in turn, states that ''[t]he Commission may, after hearing, require licensees and public utilities to carry a proper and adequate depreciation account in accordance with such rules, regulations and forms of account as the Commission may prescribe * * *.'' [16] (The Commission has, in fact, after notice and opportunity for hearing, adopted the Uniform System of Accounts,[17] which prescribes depreciation accounting procedures for public utilities and licensees.[18]) Section 302(a) goes on to state that ''[t]he licensees and public utilities subject to the jurisdiction of the Commission *shall not charge to operating expenses any depreciation charges on classes of property other than those prescribed by the Commission, or charge with respect to any class of property a percentage of depreciation other than that prescribed therefor by the Commission.*'' [19]

Contrary to Southern's argument, therefore, section 302 is not a mere enabling provision, but, rather, expressly imposes a mandatory obligation on public utilities and licensees not only to comply with the Commission's regulations governing depreciation accounting, but, more importantly for present purposes, to employ as depreciation charges and rates only those charges and rates that have been prescribed by the Commission.[20] Section 302 thus requires that before a public utility or licensee may change its depreciation rates for accounting purposes it must secure Commission authorization to do so.

Nor are we persuaded by Southern's argument that it was denied notice and opportunity to comment as required by the APA and the Due Process Clause of the United States Constitution. We believe that the May 15 order did little more than reiterate the statutory obligation imposed on public utilities and licensees by Congress in 1935—reminding public utilities and licensees of the obligation to file, according them an amnesty period to do so, and suggesting how they might wish to structure their filings. Thus, we believe that the May 15 order properly may be characterized as an ''interpretative rule'' exempt from the formal notice and comment procedures of the APA.[21] Courts have found that an interpretative rule is merely a statement of what an agency thinks a given statute or regulation means, and thus only reminds affected parties of their duties.[22] In *Fertilizer Institute, et al.* v. *EPA*, 935 F.2d 1303, 1308 (D.C. Cir. 1991), the United States Court of Appeals for the District of Columbia Circuit explained that ''as a general rule, an agency can declare its understanding of what a statute requires without providing notice and comment * * *.'' The court also explained that agency action does not require notice and comment merely because if it ''affect[s] how parties act * * *—regardless of the consequences of a rulemaking, a rule will be considered interpretative if it represents an agency's explanation of a statutory provision.''

In *American Mining Congress, et al.* v. *Mine Safety & Health Administration, et al.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993),[23] the court determined that, in contrast to an ''interpretative rule,'' an agency's rule is a ''legislative rule,'' and thus subject to the formal notice and comment procedures of the APA, if any of the following questions could be answered in the affirmative:

(1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure that the performance of duties, (2) whether the agency has published the rule in the Code of Federal Regulations, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative rule.

The May 15 order does not require an affirmative answer to any of these questions. First, as noted, section 302(a) of the FPA expressly requires public utilities and licensees to employ as their depreciation charges and rates only those charges and rates that have been prescribed by the Commission, and thus to secure Commission authorization to change their depreciation rates for accounting purposes. Accordingly, there is no legislative gap that required the May 15 order as a predicate to enforcement action. Nor did the Commission purport to act legislatively either by including the May 15 order in

[15] *Accord*, H.R. Rep. No. 74–1318, at 30 (1935); S. Rep. No. 74–621, at 53 (1935). The Commission's authority to prescribe a uniform system of accounts and to require jurisdictional utilities to keep accounts in the manner prescribed is well-settled. *See* Kansas Gas and Electric Company, 43 FERC ¶ 61,248 at 61, 675 (1988); *accord*, Union Electric Company, 52 FERC ¶ 61,279 at 62,109 (1990) (*Union Electric*).

This commission is not bound by a state commission's determinations regarding either accounting or ratemaking. *See, e.g., Union Electric*, 52 FERC at 62,112 (*citing* Kentucky Utilities Company v. FERC, 760 F.2d 1321, 1327 (D.C. Cir. 1985)).

[16] *Accord*, H.R. Rep. No. 74–1318, at 31 (1935).

[17] *See, e.g.*, Uniform System of Accounts Prescribed for Class A and Class B Public Utilities and Licensees, 23 FPC 772, 773–74 (1960).

[18] *See e.g.*, 18 CFR Part 101, Definition 12 and Account 108 (1996).

[19] *Accord*, H.R. Rep. No. 74–1318, at 31 (1935).

[20] *See Midwest Power*, 67 FERC at 61,209–09. As the Commission stated in *Midwest Power*, 67 FERC at 61,208, the Commission has a ''statutory obligation to ensure that proper amounts of depreciation are charged to expense in each financial reporting period.''

[21] Under the APA, 5 U.S.C. § 553(b)(A) (1994), the notice requirements otherwise applicable to notices of proposed rulemaking are not required for ''interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice, * * *'' unless specifically required by statute. Additionally, the FPA itself contains no requirement for formal notice and comment procedures. *See* 16 U.S.C. § 825h (1994); *accord*, 16 U.S.C. §§ 825(a), 825a(a) (1994) (sections 301 and 302 of the FPA nowhere specifically provide for formal notice and comment procedures before the Commission may adopt rules and regulations applicable to accounting or depreciation).

Moreover, consistent with the Commission's practice to publish notice of requests to change depreciation rates for accounting practices, *see supra* note 13, Midwest Power's request for declaratory order in this proceeding was noticed in the **Federal Register**. *See* 79 FERC at 61,794; 59 Fed. Reg. 55, 472 (1994). We note that the Iowa Utilities Board filed a notice of intervention in response to the **Federal Register** notice and thus was a party to the proceeding, *see* 79 FERC at 61,794, but it did not file in response to the May 15 order.

[22] *See, e.g.*, General Motors Corp. v. Ruckelshaus, 742 F.2d 1561, 1565 (D.C. Cir. 1984), *cert. denied*, 471 U.S. 1074 (1985); *accord*, Orengo Caraballo v. Reich, 11 F.3d 186, 195 (D.C. Cir. 1993); United Technologies Corp. v. EPA, 821 F.2d 714, 718-20 (D.C. Cir. 1987).

[23] *Accord*, National Wildlife Federation v. Babbitt, 835 F. Supp. 654, 666–67 (D.D.C. 1993).

the Code of Federal Regulations or by invoking its general legislative authority under Part II of the FPA. Finally, the May 15 order does not constitute an amendment of a prior legislative rule. We conclude, therefore, that the May 15 order is an interpretative rule.

Moreover, in this regard, the May 15 order did not set a depreciation rate for accounting purposes for Southern (or any public utility or licensee).[24] It merely reminded all public utilities and licensees of the need to obtain Commission authorization for changes in their depreciation rates for accounting purposes.

We also are not persuaded by Southern's arguments that changes in the electric utility industry somehow warrant allowing entities not to comply with the requirement that we approve their depreciation rates for accounting purposes. While Southern suggests that the movement to market-based power sales rates warrants our relieving public utilities and licensees of the requirement that they file, the fact is that there yet remain many cost-based power sales rates, as well as cost-based transmission rates, that reflect the companies' depreciation rates.[25] Nevertheless, we have strived to comply with out statutory responsibilities in the least burdensome, and the most expeditious, manner possible. Our intent is not to unduly burden the industry, but to fulfill our statutory responsibilities. Thus, we have allowed an amnesty period until the end of the year for these filings. Additionally, we allow these filings to be made under Rule 204 of the Commission's Rules of Practice and Procedure, 18 CFR § 285.204 (1996), which does not require payment of a filing fee. We also expect that the vast majority of these filings can be processed expeditiously by the Office of the Chief Accountant.[26]

Finally, we disagree with Southern's contention that this Commission should regulate depreciation accounting practices of jurisdictional public utilities only to the extent that the underlying capital is dedicated to jurisdictional service. The Commission's authority to prescribe a uniform system of accounts and to require a public utility to keep accounts accordingly is not open to doubt.[27] If a state desires a utility to keep a separate set of books for retail ratemaking purposes, however, the state is free to direct the utility to do so.[28]

**The Commission orders**

(A) Southern's motion to intervene out of time is hereby granted, as discussed in the body of this order.

(B) Southern's request for rehearing is hereby denied, as discussed in the body of this order.

(C) The Secretary shall promptly publish a copy of this order in the **Federal Register**.

(D) The Secretary shall promptly serve copies of this order on all State commissions, as defined in section 3(15) of the Federal Power Act.

By the Commission.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–28540 Filed 10–27–97; 8:45 am]

BILLING CODE 6717–01–M

[24] Indeed, even Midwest Power's request for a declaratory order was dismissed, as Midwest Power's depreciation rate change for accounting purposes was effective prior to *Midwest Power* and was based on sound depreciation accounting practices. 70 FERC at 61,793.

[25] *See, e.g.,* American Municipal Power-Ohio, Inc., *et al.,* 57 FERC ¶ 61,358 at 62,161 & n.5 (1991), *reh'g denied,* 58 FERC ¶ 61,182 (1992). For power marketers or other entities that only sell at market-based rates, the Commission does not prescribe depreciation rates for accounting purposes. Indeed, the Commission's accounting requirements under Part 101 of its regulations are typically waived for such entities. *See, e.g.,* PEC Energy Marketing, Inc. 79 FERC ¶ 61,329 at 62,433 (1997). Accordingly, those entities would not need to submit any filings pursuant to section 302 of the FPA.

[26] *See* 79 FERC at 61,794 n.8.

[27] *See supra* note 15 and accompanying text.

[28] Arkansas Power & Light Co. v. FPC, 185 F.2d 751, 752 (D.C. Cir. 1950), *cert. denied,* 341 U.S. 909 91951); *accord,* H.R. Rep. No. 74–1318, at 30–31 (1935); S. Rep. No. 74–621, at 53 (1935).

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket Nos. CP98–29–000, CP98–30–000, CP98–31–000, and CP98–32–000]**

### North Atlantic Pipeline Partners, L.P.; Notice of Applications for Certificates of Public Convenience and Necessity, and for a Presidential Permit and Section 3 Authorization

October 22, 1997.

Take notice that on October 15, 1997, North Atlantic Pipeline Partners, L.P. (North Atlantic), 7500 Texas Commerce Tower, 600 Travis, Houston, Texas 77002, filed applications pursuant to Sections 3 and 7(c) of the Natural Gas Act (NGA). In Docket No. CP98–29–000, North Atlantic seeks a Presidential Permit and Section 3 authorization pursuant to Part 153 of the Commission's Regulations. In Docket No. CP98–30–000, North Atlantic seeks a Certificate of Public Convenience And Necessity to construct and operate natural gas pipeline facilities under Part 157, Subpart E of the Commission's Regulations.[1] In Docket No. CP98–31–000, North Atlantic seeks a Certificate of Public Convenience And Necessity for the transportation of natural gas under Part 284, Subpart G of the Commission's Reglations. Finally, in Docket No. CP98–32–000, North Atlantic seeks a Certificate of Public Convenience And Necessity for certain blanket construction and operation authorization under Part 157, Subpart F of the Commission's Regulations. North Atlantic's proposal is more fully set forth in the applications which are on file with the Commission and open to public inspection.

North Atlantic is a limited partnership formed under the laws of the State of Delaware. North Atlantic's general partner is North Atlantic Pipeline Company, L.L.C., a Delaware limited liability company, and North Atlantic's limited partner is Tatham Offshore, Inc. North Atlantic anticipates admitting additional limited partners.

In Docket No. CP98–30–000, North Atlantic wants authority to construct, own, operate and maintain about 190 miles of 42-inch diameter pipeline under Section 7(c) of the NGA and the Commission's optional certificate procedure under Part 157, Subpart E of the Commission's Regulations. The pipeline will extend from the United States-Canada International Boundary in the Gulf of Maine to a proposed point of interconnection in East Kingston, New Hampshire with the Joint Pipeline currently authorized to be owned by Maritimes & Northeast Pipeline, L.L.C. and Portland Natural Gas Tranmission System. About 179 miles of the pipeline will be offshore and about 11 miles will be onshore. The total estimated cost of the United States portion of the project is $472 million. (The Canadian portion of the project will initially go from Country Harbor, Nova Scotia to the United States-Canadian Boundary.)

North Atlantic says the initial design capacity of the pipeline is 590,000 Mcf per day or 615,370 dekatherms per day, which is currently limited due to pressure limitations on interconnecting upstream and downstream facilities; but ultimately, as upstream offshore Atlantic Canada gas fields are further developed, North Atlantic's facilities will have the capacity to deliver up to 2,200,000 Mcf of natural gas per day on a firm basis. North Atlantic says that its project will meet a growing demand for

[1] These are the Commission's Optional Certificate procedures. In the alternative, North Atlantic seeks the same natural gas facilities construction and operation certificate under Part 157, Subpart A of the Commission's Regulations. North Atlantic filed executed Letters of Interests with 6 shippers for 269,000 MMBtu per day of capacity.

natural gas in the northeastern United States and will provide an environmentally-sound means of assessing the significant reserves of natural gas in offshore Atlantic Canada.

North Atlantic seeks approval of its initial rates and *pro forma* tariff provisions. North Atlantic proposes to offer a single rate schedule for firm transportation service, Rate Schedule FT–1, and to have the authority to negotiate, on a non-discriminatory basis, with shippers to charge rates for firm service that deviate from the FT–1 maximum rate of $12.2761, which is a cost-of-service based rate, designed under the straight-fixed variable (SFV) method and based on the design capacity of the pipeline. Rates for authorized overrun and unauthorized overrun service are also stated in North Atlantic's *pro forma* tariff.

North Atlantic has used a capital structure of 50 percent debt, 50 percent equity, an after-tax rate of return on equity of 13.25 percent and cost of debt of 7.5 percent. The initial overall after-tax rate of return under this methodology us 10.38 percent. North Atlantic has also designed its maximum cost-of-service FT–1 rate based on a 25-year plant life using straight-line depreciation.

In additional to the firm rate schedules described above, North Atlantic will offer interruptible service under Rate Schedule IT–1 at a rate of 40.36 cents per dekatherm, which is the 100 percent load factor equivalent of the maximum FT–1 rate. North Atlantic has allocated $1 million to its IT–1 service and, therefore, North Atlantic proposes to retain its Rate Schedule IT–1 revenues.

North Atlantic also proposes to negotiate, on a non-discriminatory basis, rates that differ from North Atlantic's generally applicable rate schedules. North Atlantic's negotiated rates may be less than, equal to, or greater than its cost-based maximum rates and may also be designed on a basis other than SFV. Pursuant to the Commission's Alternative Ratemaking Policy Statement, shippers unable to negotiate a satisfactory agreement are provided an option to elect the recourse rate, the maximum rate described above.

North Atlantic offers to cap the firm service rate for a long-term commitment made through the close of its open season. North Atlantic intends to negotiate with interested shippers on a non-discriminatory basis to develop agreements pursuant to which rates will automatically decrease as throughput increases over time, as an inducement to the efficient development of the vast resources to be accessed by North Atlantic.

North Atlantic's *pro forma* Tariff also includes the General Terms and Conditions (GT&C) for all transportation services, designed to meet the applicable requirements of Order No. 636, as well as standards recommended by the Gas Industry Standards Board and accepted by the Commission. North Atlantic's GT&C also include a lateral construction policy which it says is consistent with the Commission's Pricing Policy For New And Existing Facilities Constructed By Interstate Natural Gas Pipelines.

In addition, in Docket No. CP98–29–000, North Atlantic seeks authority to construct, own, operate and maintain 250 feet of 42-inch diameter pipeline at the United States-Canadian Boundary under Section 3 of the NGA and Executive Order No. 10485. At the Boundary, the pipeline will connect with North Atlantic's upstream Canadian affiliate. North Atlantic also seeks Blanket Certificates under Section 7(c) of the NGA pursuant to Part 284, Supart G and Part 157, Supbart F., in Docket Nos. CP98–31–000 and CP98–32–000, respectively, to transport natural gas for others, and perform certain routine construction functions.

Finally, North Atlantic requests a preliminary determination with respect to non-environmental issue by March 1, 1998, and a final certificate by December 1, 1998. North Atlantic has a November 1, 1999, target date for being in service.

Any person desiring to be heard or making any protest with reference to said application should on or before November 12, 1997, file with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to take but will not serve to make the protestants parties to the proceeding. The Commission's rules require that protestors provide copies of their protests to the party or person to whom the protests are directed. Any person wishing to become a party to a proceeding or to participating as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

A person obtaining intervenor status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents issued by the Commission, filed by the applicant, or filed by all other intervenors. An intervenor can file for rehearing of any Commission order and can petition for court review of any such order. However, an intervenor must serve copies of comments or any other filing it makes with the Commission to every other intervenor in the proceeding, as well as filing an original and 14 copies with the Commission.

However, a person, company or organization does not have to intervene in order to have comments on any aspect of the proposal considered by the Commission. Instead, such entity may submit two copies of such comments to the Secretary of the Commission. Commenters who are concerned about environmental or pipeline routing issues will be placed on the Commission's environmental mailing list, will receive copies of environmental documents and will be able to participate in meetings associated with the Commission's environmental review process. Commenters will not be required to serve copies of filed documents on all other parties. However, commenters will not receive copies of all documents filed by the parties or issued by the Commission, and will not have the right to seek rehearing or appeal the Commission's final order to a Federal court.

The Commission will consider all comments and concerns equally, whether filed by commenters or those requesting intervenor status.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 3, 7 and 15 of the NGA and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on these applications if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be

unnecessary for North Atlantic to appear or be represented at the hearing.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–28455 Filed 10–27–97; 8:45 am]

BILLING CODE 6717–01–M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket Nos. ER96–399–000; EL96–35–001]**

### Northern Indiana Public Service Company and Wabash Valley Power Association, Inc. v. Northern Indiana Public Service Company; Notice of Filing

October 22, 1997.

Please take notice that on August 6, 1997, Northern Indiana Public Service Company (Northern Indiana) filed its refund report in the above captioned case.

Copies of the refund report have been served on all parties and on the Indiana Utility Regulatory Commission.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with the Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions and protests should be filed on or before November 3, 1997. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–28457 Filed 10–27–97; 8:45 am]

BILLING CODE 6717–01–M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. EC98–7–000]**

### Phibro Inc.; Notice of Application for Authorization Under Federal Power Act Section 203

October 22, 1997.

Take notice that on October 21, 1997, Phibro Inc. (Phibro), tendered for filing a request that the Commission approve a disposition of facilities and/or grant any other authorization the Commission may deem to be needed under Section 203 of the Federal Power Act as a result of the forthcoming acquisition of Salomon Inc (Salomon), Phibro's parent, by Travelers Group Inc., (Travelers). As explained in the application, the planned acquisition will have no effect on the jurisdictional facilities, rates or services of Phibro and will be consistent with the public interest.

Phibro requests expeditious action on the application in order that there be no delay in the acquisition of Salomon by Travelers.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before November 21, 1997. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–28539 Filed 10–27–97; 8:45 am]

BILLING CODE 6717–01–M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. CP98–39–000]**

### Tennessee Gas Pipeline Company; Notice of Application

October 22, 1997.

Take notice that on October 20, 1997, Tennessee Gas Pipeline Company (Tennessee), 1001 Louisiana, Houston, Texas 77002, filed an application pursuant to Section 7 of the Natural Gas Act (NGA) and Part 157 of the Commission's Regulations thereunder for a certificate of public convenience and necessity authorizing the construction and operation of certain natural gas facilities and an order granting permission and approval to abandon the facilities being replaced, all as more fully set forth in the application on file with the Commission and open to public inspection.

Specifically, Tennessee requests that the Commission issue an order authorizing Tennessee to (1) abandon four 26-inch diameter pipelines which are fastened to the bridge for Highway 82 (Highway 82 Bridge) which crosses the Mississippi River near Greenville, Mississippi; (2) construct, own, and operate one 30-inch diameter pipeline; and (3) reconfigure six existing pipelines near the Mississippi River. Tennessee states that its requests are necessitated by the State of Mississippi Highway Department's (MDOT) plans to build a new bridge and remove the Highway 82 Bridge. Tennessee requests that the Commission grant the requested authorization by March 16, 1998.

Tennessee states that the proposed abandonment and construction are necessary to maintain the integrity of Tennessee's mainline transmission system and to enable Tennessee to continue to provide uninterrupted service for shippers. Tennessee states that the estimated cost for abandoning the segments of pipeline and constructing the proposed segments of pipeline will be approximately $12,337,000.

Any person desiring to participate in the hearing process or to make any protest with reference to said application should on or before November 12, 1997, file with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to take but will not serve to make the protestants parties to the proceeding. The Commission's rules require that protestors provide copies of their protests to the party or parties directly involved. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

A person obtaining intervenor status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by every one of the intervenors. An intervenor can file for rehearing of any Commission order and can petition for court review of any such order. However, an intervenor must submit copies of comments or any other filing it makes with the Commission to every

other intervenor in the proceeding, as well as 14 copies with the Commission.

A person does not have to intervene, however, in order to have comments considered. A person, instead, may submit two copies of comments to the Secretary of the Commission. Commenters will be placed on the Commission's environmental mailing list, will receive copies of environmental documents and will be able to participate in meetings associated with the Commission's environmental review process. Commenters will not be required to serve copies of filed documents on all other parties. However, commenters will not receive copies of all documents filed by other parties or issued by the Commission and will not have the right to seek rehearing or appeal the Commission's final order to a federal court.

The Commission will consider all comments and concerns equally, whether filed by commenters or those requesting intervenor status.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Tennessee to appear or be represented at the hearing.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–28456 Filed 10–27–97; 8:45 am]

BILLING CODE 6717–01–M

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Docket Nos. FA96–6–004; and RP92–137–048]**

## Transcontinental Gas Pipe Line Corporation; Notice of Report of Refunds

Take notice on October 17, 1997, Transcontinental Gas Pipe Line Corporation (Transco) tendered for filing a report of refunds pertaining to refunds distributed on September 18, 1997.

Transco states that the purpose of such refund was to comply with the Division of Audits letter order issued January 8, 1997, regarding interruptible transportation revenues related to he Spider Field lateral for the period September 1, 1992 through October 31, 1993.

Transco is servicing copies of the instant filing to customers, State Commission and other interested parties.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests should be filed on or before October 29, 1997. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–28459 Filed 10–27–97; 8:45 am]

BILLING CODE 6717–01–M

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Docket No. TM98–2–29–000]**

## Transcontinental Gas Pipe Line Corporation; Notice of Proposed Changes in FERC Gas Tariff

October 22, 1997.

Take notice that on October 17, 1997, Transcontinental Gas Pipe Line Corporation (Transco), tendered for filing its FERC Gas Tariff, Third Revised Volume No. 1, certain revised tariff sheets which are enumerated in Appendix A attached to the filing, with an effective date of October 1, 1997.

Transco states that the purpose of the instant filing is to track rate changes attributable to (1) storage service purchased from National Fuel Gas Supply Corporation (National Fuel) under its Rate Schedule SS–1, the costs of which are included in the rates and charges payable under Transco's Rate Schedules LSS and SS–2, (2) storage service purchased from CNG Transmission Corporation (CNG) under its Rate Schedule GSS, the costs of which are included in the rates and charges payable under Transco's Rate Schedules LSS and GSS, (3) transportation service purchased from National Fuel under its Rate Schedule X–54, the costs of which are included in the rates and charges payable under Transco's Rate Schedule SS–2, (4) transportation service purchased from Texas Gas Transmission Corporation (Texas Gas) under its rate schedule FT, the costs of which are included in the rates and charges payable under Transco's Rate Schedule FT–NT, and (5) storage service purchased from Texas Eastern Transmission Corporation (TETCO) under its Rate Schedule X–28, the costs of which are included in the rates and charges payable under Transco's Rate Schedule S–2.

Transco states that this tracking filing is being made pursuant to tracking provisions under Section 4 of Transco's Rate Schedule LSS, Section 4 of Transco's Rate Schedule SS–2, Section 4 of Transco's Rate Schedule FT–NT, Section 3 of Transco's Rate Schedule GSS, and Section 26 of the General Terms and Conditions of Transco's Volume No. 1 Tariff. Transco also filed therein Substitute Eighth Revised Sheet No. 28 to incorporate changes originally filed August 26, 1997 in Docket No. TM97–12–29, to be effective August 1, 1997. Such filing inadvertently omitted a change to Transco's Rate Schedule S–2 Demand Charge Adjustment.

Transco states that included in Appendices B through E attached to the filing are explanations of the rate changes and details regarding the computation of the revised Rate Schedules LSS, SS–2, FT–NT, S–2 and GSS rates.

Transco states that copies of the filing are being mailed to each of its LSS, SS–2, FT–NT, S–2 and GSS customers and interested State Commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the

Commission's Rules and Regulations. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–28465 Filed 10–27–97; 8:45 am]

BILLING CODE 6717–01–M

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## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Docket Nos. RP97–454–000 and RP97–258–003 (Not consolidated)]**

## Williams Natural Gas Company; Notice of Technical Conference

October 22, 1997.

In the Commission's order issued on September 19, 1997, in the above-captioned proceedings, the Commission held that the filing raises issues for which a technical conference is to be convened.

The conference to address the issues has been scheduled for Wednesday, November 5, 1997, at 10:00 a.m., in a room to be designated at the offices of the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426.

All interested persons and Staff are permitted to attend.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–28463 Filed 10–27–97; 8:45 am]

BILLING CODE 6717–01–M

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## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Docket No. EC97–10–000, *et al.*]**

## Consolidated Edison Company of New York, Inc. et al.; Electric Rate and Corporate Regulation Filings

October 21, 1997.

Take notice that the following filings have been made with the Commission:

### 1. Consolidated Edison Company of New York, Inc.

[Docket No. EC97–10–000]

Take notice that on October 10, 1997, Consolidated Edison Company of New York, Inc., tendered for filing an amendment in the above-referenced docket.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

### 2. Pacific Gas and Electric Company

[Docket No. ER97–4821–000]

Take notice that on September 30, 1997, Pacific Gas and Electric Company (PG&E) tendered for filing; (1) an agreement dated as of September 1, 1997, by and between PG&E and PacifiCorp entitled Service Agreement for Firm Point-to-Point Transmission Service (Service Agreement); and (2) a request for termination of this Service Agreement.

Copies of this filing have been served upon the California Public Utilities Commission and PacifiCorp.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

### 3. Southern Company Services, Inc.

[Docket No. ER97–4822–000]

Take notice that on September 30, 1997, Southern Company Services, Inc. (SCS), acting on behalf of Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company, and Savannah Electric and Power Company (collectively referred to as the Southern Company System) filed a Service Agreement for Network Integration Transmission Service under Part III of the Open Access Transmission Tariff of Southern Companies. In addition, the Southern Company System filed the corresponding Specifications for Network Integration Service, a Network Operating Agreement, and a Letter Agreement concerning certain interim arrangements that would apply until the earlier of November 1, 1997 or the date that the parties complete the installation and testing of equipment necessary to allow for dynamic scheduling.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

### 4. Florida Power Corporation

[Docket No. ER97–4823–000]

Take notice that on September 30, 1997, Florida Power Corporation (Florida Power) tendered for filing a service agreement providing for non-firm point-to-point transmission service to NP Energy, Inc. (NP), pursuant to its open access transmission tariff. Florida Power requests that the Commission waive its notice of filing requirements and allow the agreement to become effective on October 1, 1997.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

### 5. Florida Power Corporation

[Docket No. ER97–4824–000]

Take notice that on September 30, 1997, Florida Power Corporation (Florida Power) tendered for filing a service agreement providing for non-firm point-to-point transmission service to The Energy Authority, Inc. (Energy Authority), pursuant to its open access transmission tariff. Florida Power requests that the Commission waive its notice of filing requirements and allow the agreement to become effective on October 1, 1997.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

### 6. Florida Power Corporation

[Docket No. ER97–4825–000]

Take notice that on September 30, 1997, Florida Power Corporation (Florida Power) tendered for filing a service agreement providing for firm point-to-point transmission service to The Energy Authority, Inc. (Energy Authority), pursuant to its open access transmission tariff. Florida Power requests that the Commission waive its notice of filing requirements and allow the agreement to become effective on October 1, 1997.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

### 7. Tucson Electric Power Company

[Docket No. ER97–4826–000]

Take notice that on September 30, 1997, Tucson Electric Power Company (TEP) tendered for filing one (1) service agreement for firm point-to-point transmission service under Part II of its Open Access Transmission Tariff filed in Docket No. OA96–140–000. TEP requests waiver of notice to permit the service agreement to become effective as of the earliest date service commenced under this agreement. The details of the service agreement are as follows:

1. Service Agreement for Firm Point-to-Point Transmission Service with Enron Power Marketing, Inc. dated September 11, 1997. Service under this agreement commenced on September 1, 1997.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**8. Rochester Gas and Electric Corporation**

[Docket No. ER97–4827–000]

Take notice that on September 30, 1997, Rochester Gas and Electric Corporation (RG&E) filed a Service Agreement between RG&E and the Cinergy Corp., (Customer). This Service Agreement specifies that the Customer has agreed to the rates, terms and conditions of the RG&E open access transmission tariff filed on July 9, 1996 in Docket No. OA96–141–000.

RG&E requests waiver of the Commission's sixty (60) day notice requirements and an effective date of September 19, 1997, for the Cinergy Corp., Service Agreement. RG&E has served copies of the filing on the New York State Public Service Commission and on the Customer.

*Comment date*: November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**9. Northeast Utilities Service Company**

[Docket No. ER97–4828–000]

Take notice that Northeast Utilities Service Company (NUSCO), on September 30, 1997, tendered for filing, a Service Agreement with the Carolina Power and Light Company under the NU System Companies' Sale for Resale, Tariff No. 7.

NUSCO states that a copy of this filing has been mailed to the Carolina Power and Light Company.

NUSCO requests that the Service Agreement become effective September 16, 1997.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**10. Zond Minnesota Development Corporation II and Lake Benton Power Partners, LLC**

[Docket No. ER97–4831–000]

Take notice that on September 26, 1997, Zond Minnesota Development Corporation II and Lake Benton Power Partners, LLC tendered for filing Notice of Succession in the above-referenced docket.

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**11. Additional Signatories to PJM Interconnection, L.L.C. Operating Agreement**

[Docket No. ER98–1–000]

Take notice that on October 1, 1997, the PJM Interconnection, L.L.C. (PJM) filed, on behalf of the Members of the LLC, membership application of Engelhard Power Marketing, Inc., and QST Energy Trading. PJM requests an effective date of October 3, 1997.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**12. Ohio Valley Electric Corporation; Indiana-Kentucky Electric Corporation**

[Docket No. ER98–2–000]

Take notice that on October 1, 1997, Ohio Valley Electric Corporation (including its wholly-owned subsidiary, Indiana-Kentucky Electric Corporation) (OVEC) tendered for filing a Service Agreement for Non-Firm Point-To-Point Transmission Service, dated September 19, 1997 (the Service Agreement) between LG&E Energy Marketing, Inc. (LG&E Marketing), and OVEC. OVEC proposes an effective date of September 19, 1997 and requests waiver of the Commission's notice requirement to allow the requested effective date. The Service Agreement provides for non-firm transmission service by OVEC to LG&E Marketing.

In its filing, OVEC states that the rates and charges included in the Service Agreement are the rates and charges set forth in OVEC's Open Access Transmission Tariff.

A copy of this filing was served upon LG&E Marketing.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**13. Commonwealth Electric Company; Cambridge Electric Light Company**

[Docket No. ER98–4–000]

Take notice that on October 1, 1997, Commonwealth Electric Company (Commonwealth) and Cambridge Electric Light Company (Cambridge), collectively referred to as the Companies, tendered for filing with the Federal Energy Regulatory Commission executed Service Agreements between the Companies and the following Market-Based Power Sales Customers (collectively referred to herein as the Customers): Engage Energy US, L.P., South Carolina Electric & Gas Company, Williams Energy Services Company, WPS Energy Services, Inc.

These Service Agreements specify that the Customers have signed on to and have agreed to the terms and conditions of the Companies' Market-Based Power Sales Tariffs designated as Commonwealth's Market-Based Power Sales Tariff (FERC Electric Tariff Original Volume No. 7) and Cambridge's Market-Based Power Sales Tariff (FERC Electric Tariff Original Volume No. 9). These Tariffs, accepted by the FERC on February 27, 1997, and which have an effective date of February 28, 1997, will allow the Companies and the Customers to enter into separately scheduled short-term transactions under which the Companies will sell to the Customers capacity and/or energy as the parties may mutually agree.

The Companies and Engage Energy US have also filed Notices of Cancellation for service under the Companies' Power Sales and Exchange Tariffs (FERC Electric Tariff Original Volume Nos. 5 and 3) and Engage Energy US's respective FERC Rate Schedules.

The Companies request an effective date as specified on each Service Agreement and Notice of Cancellation.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**14. Idaho Power Company**

[Docket No. ER98–5–000]

Take notice that on October 1, 1997, Idaho Power Company (IPC), tendered for filing with the Federal Energy Regulatory Commission a Service Agreement under Idaho Power Company FERC Electric Tariff, Second Revised, Volume No. 1 between Black Hills Power & Light and Idaho Power Company.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**15. UtiliCorp United Inc.**

[Docket No. ER98–7–000]

Take notice that on October 2, 1997, UtiliCorp United Inc. (UtiliCorp), filed service agreements with Northern States Power Company for service under its non-firm point-to-point open access service tariff for its operating divisions, Missouri Public Service and WestPlains Energy—Kansas.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**16. Indiana Michigan Power Company**

[Docket No. ER98–8–000]

Take notice that on October 1, 1997, Indiana Michigan Power Company (I&M), tendered for filing with the Commission Facility Request No. 10 to the existing Agreement, dated December 11, 1989, (1989 Agreement), between I&M and Wabash Valley Power Association, Inc., (WVPA). Facility Request No. 10 was negotiated in response to WVPA's request that I&M provide new facilities at two existing 69 kV tap stations to be owned by WVPA and operated by I&M known as Fruit Belt Electric Cooperative—Schoolcraft and White Pigeon Tap Stations. The Commission has previously designated

the 1989 Agreement as I&M's Rate Schedule FERC No. 81.

As requested by, and for the sole benefit of WVPA, I&M proposes an effective date of December 1, 1997, for Facility Request No. 10. A copy of this filing was served upon WVPA, the Indiana Utility Regulatory Commission, and the Michigan Public Service Commission.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**17. Puget Sound Energy, Inc.**

[Docket No. ER98–9–000]

Take notice that on October 2, 1997, Puget Sound Energy, Inc. (Puget), tendered for filing, as a change in rate schedule, an Amendment No. 1 to Power Exchange Agreement (the Amendment) by and between Puget and British Columbia Power Exchange Corporation (Powerex). A copy of the filing was served upon Powerex.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**18. Cleveland Electric Illuminating Company and The Toledo Edison Company**

[Docket No. ER98–10–000]

Take notice that on October 2, 1997, the Centerior Service Company as Agent for The Cleveland Electric Illuminating Company and The Toledo Edison Company filed Service Agreements to provide Non-Firm Point-to-Point Transmission Service for Koch Energy Trading Inc., the Transmission Customer. Services are being provided under the Centerior Open Access Transmission Tariff submitted for filing by the Federal Energy Regulatory Commission in Docket No. OA96–204–000. The proposed effective date under the Service Agreement is July 28, 1997.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**19. Long Island Lighting Company**

[Docket No. ER98–11–000]

Take notice that on October 1, 1997, Long Island Lighting Company (LILCO), tendered for filing a Power Supply Agreement for the sale of energy and capacity by LILCO (through a generation subsidiary to be formed) to the Long Island Power Authority (LIPA).

LILCO requests an effective date of April 1, 1998 and a waiver of 18 CFR 35.3.

Copies of the filing were served upon LIPA and the New York State Public Service Commission.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**20. Sierra Pacific Power Company**

[Docket No. ER98–12–000]

Take notice that on October 2, 1997, Sierra Pacific Power Company (Sierra Pacific), filed revised open-access tariff sheets to provide for Retail Access Transmission Service.

Sierra Pacific proposes that these revised tariff sheets become effective January 1, 1998.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**21. Enron Energy Services Power, Inc.**

[Docket No. ER98–13–000]

Take notice that on October 1, 1997, Enron Energy Services Power, Inc. (EES) applied to the Commission for acceptance of EES Rate Schedule FERC No. 1; the granting of certain blanket approvals, including the authority to sell electricity at market-based rates; and the waiver of certain Commission regulations.

EES intends to engage in wholesale electric power and energy purchases and sales as a marketer.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**22. Cinergy Services, Inc.**

[Docket No. ER98–14–000]

Take notice that on October 2, 1997, Cinergy Services, Inc. (Cinergy), tendered for filing a service agreement under Cinergy's Open Access Transmission Service Tariff (the Tariff) entered into between Cinergy and New Energy Ventures, L.L.C. (Ventures).

Cinergy and Ventures are requesting an effective date of September 30, 1997.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**23. Cinergy Services, Inc.**

[Docket No. ER98–15–000]

Take notice that on October 2, 1997, Cinergy Services, Inc. (Cinergy), tendered for filing a service agreement under Cinergy's Open Access Transmission Service Tariff (the Tariff) entered into between Cinergy and Duke Energy Trading and Marketing, L.L.C. (Duke).

Cinergy and Duke are requesting an effective date of September 30, 1997.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**24. Cinergy Services, Inc.**

[Docket No. ER98–16–000]

Take notice that on October 2, 1997, Cinergy Services, Inc. (Cinergy), tendered for filing a service agreement under Cinergy's Open Access Transmission Service Tariff (the Tariff) entered into between Cinergy and New Energy Ventures, L.L.C. (Ventures).

Cinergy and Ventures are requesting an effective date of September 30, 1997.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**25. Central Illinois Public Service Company**

[Docket No. ER98–17–000]

Take notice that on October 2, 1997, Central Illinois Public Service Company (CIPS), submitted an executed non-firm point-to-point service agreement, dated September 22, 1997, establishing Avista Energy, Inc. as a customer under the terms of CIPS' Open Access Transmission Tariff.

CIPS requests an effective date of September 22, 1997 for the service agreement. Accordingly, CIPS requests waiver of the Commission's notice requirements. Copies of this filing were served on Avista Energy, Inc. and the Illinois Commerce Commission.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**26. Kansas City Power & Light Company**

[Docket No. ER98–18–000]

Take notice that on October 2, 1997, Kansas City Power & Light Company (KCPL), tendered for filing a Service Agreement dated August 29, 1997, between KCPL and MidAmerica Energy Company. KCPL proposes an effective date of September 26, 1997, and requests waiver of the Commission's notice requirement. This Agreement provides for the rates and charges for Non-Firm Transmission Service.

In its filing, KCPL states that the rates included in the above-mentioned Service Agreement are KCPL's rates and charges in the compliance filing to FERC Order No. 888–A in Docket No. OA97–636.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**27. Kansas City Power & Light Company**

[Docket No. ER98–19–000]

Take notice that on October 2, 1997, Kansas City Power & Light Company (KCPL), tendered for filing a Service Agreement dated September 17, 1997,

between KCPL and Aquila Power Corporation. KCPL proposes an effective date of September 17, 1997, and requests waiver of the Commission's notice requirement. This Agreement provides for Non-Firm Power Sales Service.

In its filing, KCPL states that the rates included in the above-mentioned Service Agreement are pursuant to KCPL's compliance filing in Docket No. ER94–1045.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**28. Kansas City Power & Light Company**

[Docket No. ER98–20–000]

Take notice that on October 2, 1997, Kansas City Power & Light Company (KCPL), tendered for filing a Service Agreement dated September 26, 1997, between KCPL and NP Energy, Inc. KCPL proposes an effective date of September 26, 1997, and requests waiver of the Commission's notice requirement. This Agreement provides for Non-Firm Power Sales Service.

In its filing, KCPL states that the rates included in the above-mentioned Service Agreement are pursuant to KCPL's compliance filing in Docket No. ER94–1045.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**29. California Power Exchange**

[Docket No. ER98–210–000]

Take notice that on October 17, 1997, the California Power Exchange Corporation (PX) tendered for filing its PX Administration Charge as required under its FERC Tariff. This filing is made pursuant to Commission direction in Pacific Gas & Electric Co. *et al.*, 77 FERC ¶ 61,204, at 51,804 (1996) in which the Commission ordered the PX to file its rate schedules pursuant to Section 205(c) of the Federal Power Act.

Copies of the filing were served upon all parties to Docket Nos. EC96–19–003 and ER96–1663–003, the California Public Utilities Commission, and all other affected entities.

*Comment date:* November 7, 1997, in accordance with Standard Paragraph E at the end of this notice.

**30. California Independent System Operator Corporation**

[Docket No. ER98–211–000]

Take notice that on October 17, 1997, the California Independent System Operator Corporation (ISO) tendered for filing proposed rates under Section 205 of the Federal Power Act for its FERC Electric Service Tariffs.

Pursuant to Section 35.13(a)(1) of the Commission's Regulations, 18 CFR 35.13(a)(1), the California Independent System Operator Corporation (ISO) seeks approval of the Grid Management Charge and rate schedules for approval of certain pass-through charges for Ancillary Services, Congestion Management and Wheeling Access. The ISO requests that these rates be allowed to go into effect on January 1, 1998.

Copies of the filing were served upon the entities contained in the official service list for Pacific Gas & Electric Company, *et al.*, Docket Nos. EC96–19–003 and ER96–1663–003 and the California Public Utilities Commission.

*Comment date:* November 7, 1997, in accordance with Standard Paragraph E at the end of this notice.

**Standard Paragraph**

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–28535 Filed 10–27–97; 8:45 am]

BILLING CODE 6717–01–P

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## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Docket No. ER97–4629–000, et al.]**

## Golden Spread Electric Cooperative, Inc., et al. Electric Rate and Corporate Regulation Filings

October 22, 1997.

Take notice that the following filings have been made with the Commission:

**1. Golden Spread Electric Cooperative, Inc.**

[Docket No. ER97–4629–000]

Take notice that on September 16, 1997, Golden Spread Electric Cooperative, Inc. (Golden Spread), tendered its Special Facilities Agreement with Tri-County Electric Cooperative, Inc. (Tri-County) pursuant to § 35.13 of the Commission's Regulations. The Special Facilities Agreement between Golden Spread and Tri-County provides for the construction and ownership of a 115/12.47 kV substation to be located outside of Guymon, Oklahoma. The charges associated with the construction and ownership of this facility will be recovered by Golden Spread from Tri-County pursuant to Rider A of Rate Schedule FERC No. 22. The filing will not effect a rate increase or decrease to Golden Spread's Members.

Copies of this filing were served upon Golden Spread's jurisdictional customers, the Public Utility Commission of Texas, and the Oklahoma Corporation Commission.

*Comment date:* November 4, 1997, in accordance with Standard Paragraph E at the end of this notice.

**2. Kansas City Power & Light Company**

[Docket No. ER98–21–000]

Take notice that on October 2, 1997, Kansas City Power & Light Company (KCPL), tendered for filing a Service Agreement dated September 26, 1997, between KCPL and ConAgra Energy Services, Inc. KCPL proposes an effective date of September 26, 1997, and requests waiver of the Commission's notice requirement. This Agreement provides for Non-Firm Power Sales Service.

In its filing, KCPL states that the rates included in the above-mentioned Service Agreement are pursuant to KCPL's compliance filing in Docket No. ER94–1045.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**3. Maine Electric Power Company**

[Docket No. ER98–22–000]

Take notice that on October 6, 1997, Maine Electric Power Co. (MEPCO), tendered for filing pursuant to Part 35 of the Federal Energy Regulatory Commission's Rules of Practice and Procedure, 18 CFR Part 35, a Letter Agreement amending the term of two service agreements entered into with Bangor Hydro-Electric Company (BHE), one dated July 9, 1996, and the other dated July 24, 1996 (each as accepted for filing in Docket No. ER96–2634–000), under which MEPCO is providing Firm Point-to-Point Transmission Service in accordance with the MEPCO Open Access Transmission Tariff (the Tariff). The Letter Agreement extends the term of the Service Agreements to October 31, 1998.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**4. Portland General Electric Company**

[Docket No. ER98–23–000]

Take notice that on October 3, 1997, Portland General Electric Company (PGE), tendered for filing under PGE's Final Rule pro forma tariff (FERC Electric Tariff Original Volume No. 8, Docket No. OA96–137–000), an executed Service Agreement for Non-Firm Point-to-Point Transmission Service with NP Energy Inc.

Pursuant to 18 CFR 35.11, and the Commission's Order in Docket No. PL93–2–002 issued July 30, 1993, PGE respectfully requests that the Commission grant a waiver of the notice requirements of 18 CFR 35.3 to allow the Service Agreement to become effective September 15, 1997.

A copy of this filing was caused to be served upon NP Energy Inc., as noted in the filing letter.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**5. Union Electric Company**

[Docket No. ER98–24–000]

Take notice that on October 3, 1997, Union Electric Company (UE), tendered for filing Service Agreements for Market Based Rate Power Sales between UE and Federal Energy Sales, Inc., Minnesota Power & Light Company and Wisconsin Electric Power Company. UE asserts that the purpose of the Agreements is to permit UE to make sales of capacity and energy at market based rates to the parties pursuant to UE's Market Based Rate Power Sales Tariff filed in Docket No. ER97–3664–000.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**6. Union Electric Company**

[Docket No. ER98–25–000]

Take notice that on October 3, 1997, Union Electric Company (UE), tendered for filing Service Agreements for Non-Firm Point-to-Point Transmission Services between UE and Avista Energy, Inc., and The Dayton Power and Light Company. UE asserts that the purpose of the Agreements is to permit UE to provide transmission service to the parties pursuant to UE's Open Access Transmission Tariff filed in Docket No. OA96–50.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**7. Central Maine Power Company**

[Docket No. ER98–26–000]

Take notice that on October 6, 1997, Central Maine Power Company filed an amendment to Central Maine Power's Wholesale Market Tariff, FERC Electric Tariff, Original Volume No. 4 (Tariff No. 4). Central Maine Power proposes to add new Section Z under which it will be able to sell, assign or transfer to a Tariff No. 4 customer all or a portion of its rights to transmission service acquired under a transmission provider's open access transmission tariff, provided, that the customer is an eligible customer under the transmission provider's open access transmission tariff.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**8. Western Resources, Inc.**

[Docket No. ER98–27–000]

Take notice that on October 3, 1997, Western Resources, Inc., tendered for filing a non-firm transmission agreement between Western Resources and Cinergy Operating Companies. Western Resources states that the purpose of the agreement is to permit non-discriminatory access to the transmission facilities owned or controlled by Western Resources in accordance with Western Resources' open access transmission tariff on file with the Commission. The agreement is proposed to become effective September 26, 1997.

Copies of the filing were served upon Cinergy Operating Companies and the Kansas Corporation Commission.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**9. Northern Indiana Public Service Company**

[Docket No. ER98–29–000]

Take notice that on October 3, 1997, Northern Indiana Public Service Company, tendered for filing an executed Standard Transmission Service Agreement for Non-Firm Point-to-Point Transmission Service between Northern Indiana Public Service Company and The Dayton Power and Light Company.

Under the Transmission Service Agreement, Northern Indiana Public Service Company will provide Point-to-Point Transmission Service to The Dayton Power and Light Company pursuant to the Transmission Service Tariff filed by Northern Indiana Public Service Company in Docket No. OA96–47–000 and allowed to become effective by the Commission. Northern Indiana Public Service Company has requested that the Service Agreement be allowed to become effective as of September 8, 1997.

Copies of this filing have been sent to the Indiana Utility Regulatory Commission and the Indiana Office of Utility Consumer Counselor.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**10. Central Hudson Gas and Electric Corporation**

[Docket No. ER98–30–000]

Take notice that on October 3, 1997, Central Hudson Gas and Electric Corporation (CHG&E), tendered for filing pursuant to 35.12 of the Federal Energy Regulatory Commission's (Commission) Regulations in 18 CFR a Service Agreement between CHG&E and Constellation Power Source (CPS). The terms and conditions of service under this Agreement are made pursuant to CHG&E's FERC Electric Rate Schedule, Original Volume No. 1 (Power Sales Tariff) accepted by the Commission in Docket No. ER97–890–000. CHG&E also has requested waiver of the 60-day notice provision pursuant to 18 CFR 35.11.

A copy of this filing has been served on the Public Service Commission of the State of New York.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**11. Kentucky Utilities Company**

[Docket No. ER98–31–000]

Take notice that on October 3, 1997, Kentucky Utilities Company (KU), tendered for filing a Notice of Cancellation of its Service Agreement under the Power Services Tariff as approved by the Commission in Docket No. ER97–2700–000 with Coastal Electric Services. This Agreement is being canceled because it was inadvertently filed in that Docket. The Commission had previously approved the same Service Agreement in Docket No. ER97–502–000.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**12. Southern California Edison Company**

[Docket No. ER98–32–000]

Take notice that on October 3, 1997, Southern California Edison Company (Edison), tendered for filing the following Termination Agreement (Termination Agreement) and Non-Firm Supplemental Agreement (Non-Firm Supplemental Agreement) to the 1990 Integrated Operations Agreement (1990

IOA) between the City of Anaheim (Anaheim) and Edison, FERC Rate Schedule No. 246:

Termination of Supplemental Agreement For The Integration Of Anaheim's Entitlement In San Juan Unit 4

Supplemental Agreement For The Integration Of Non-Firm Energy From Anaheim's Entitlement In San Juan Unit 4 Between Southern California Edison Company And City Of Anaheim

The Termination Agreement cancels the Supplemental Agreement for the integration of firm capacity and associated energy purchased by Anaheim under the San Juan Unit 4 Agreement.

The Non-Firm Supplemental Agreement sets forth the terms and conditions by which Edison will integrate Anaheim's entitlement to energy from San Juan Unit 4 as a source of Non-Firm Energy in accordance with the terms of the 1990 IOA.

Edison is requesting waiver of the 60-day prior notice requirement, and requests that the Commission assign to the Termination Agreement and Non-Firm Supplemental Agreement effective dates of November 1, 1997.

Copies of this filing were served upon the Public Utilities Commission of the State of California and all interested parties.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**13. Portland General Electric Company**

[Docket No. ER98–34–000]

Take notice that on October 3, 1997, Portland General Electric Company (PGE) tendered for filing under PGE's Final Rule pro forma tariff (FERC Electric Tariff Original Volume No. 8, Docket No. OA96–137–000), an executed Service Agreement for Non-Firm Point-to-Point Transmission Service with Kansas City Power and Light Company.

Pursuant to 18 CFR 35.11, and the Commission's Order in Docket No. PL93–2–002 issued July 30, 1993, PGE respectfully requests that the Commission grant a waiver of the notice requirements of 18 CFR 35.3 to allow the Service Agreement to become effective September 16, 1997.

A copy of this filing was caused to be served upon Kansas City Power and Light Company as noted in the filing letter.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**14. Kentucky Utilities Company**

[Docket No. ER98–35–000]

Take notice that on October 3, 1997, Kentucky Utilities Company (KU), tendered for filing service agreements between KU and The Energy Authority, Inc., Dayton Power & Light, Proliance Energy, LLC, Western Resources and Public Service Electric and Gas Company under its Transmission Services (TS) Tariff and with The Energy Authority, Inc., under its Power Services (PS) Tariff.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**15. New England Power Pool**

[Docket No. ER98–36–000]

Take notice that on October 3, 1997, the New England Power Pool Executive Committee filed for acceptance a signature page to the New England Power Pool (NEPOOL) Agreement dated September 1, 1971, as amended, signed by Delmarva Power & Light Company (Delmarva). The NEPOOL Agreement has been designated NEPOOL FPC No. 2.

The Executive Committee states that the Commission's acceptance of Delmarva's signature page would permit NEPOOL to expand its membership to include Delmarva. NEPOOL further states that the filed signature page does not change the NEPOOL Agreement in any manner, other than to make Delmarva a member in NEPOOL. NEPOOL requests an effective date of October 6, 1997, for commencement of participation in NEPOOL by Delmarva.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**16. Southern Company Services, Inc.**

[Docket No. ER98–37–000]

Take notice that on October 6, 1997, Southern Company Services, Inc. (SCS), acting as agent for Alabama Power Company (APCo), tendered for filing a Delivery Point Specification Sheet dated as of July 29, 1997, reflecting the abandonment of two delivery points to the City of Lanett Electric Department. The abandoned delivery points will no longer be served under the terms and conditions of the Amended and Restated Agreement for Partial Requirements Service and Complementary Services between Alabama Power Company and the Alabama Municipal Electric Authority dated June 16, 1994.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**17. Duquesne Light Company**

[Docket No. ER98–38–000]

Take notice that on October 6, 1997, Duquesne Light Company (DLC) filed a Service Agreement dated September 30, 1997 with NP Energy under DLC's Open Access Transmission Tariff (Tariff). The Service Agreement adds NP Energy as a customer under the Tariff. DLC requests an effective date of September 30, 1997, for the Service Agreement.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**18. Atlantic City Electric Company**

[Docket No. ER98–39–000]

Take notice that on October 6, 1997, Atlantic City Electric Company (Atlantic Electric), tendered for filing a service agreement under which Atlantic Electric will sell capacity and energy to Valero Power Services Company (Valero) under Atlantic Electric's market-based rate sales tariff. Atlantic Electric requests the agreement be accepted to become effective on September 15, 1997.

Atlantic Electric states that a copy of the filing has been served on Valero.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**19. Central Illinois Public Service Company**

[Docket No. ER98–40–000]

Take notice that on October 6, 1997, Central Illinois Public Service Company (CIPS), tendered for filing Service Schedule K to the Power Supply Agreement between CIPS and the Illinois Municipal Electric Agency (IMEA); revised Schedule 8 to the Transmission Service Agreement between CIPS and IMEA; and a Notice of Cancellation of CIPS' service to the Village of Greenup, Illinois (Greenup). Upon the effectiveness of these agreements, Greenup will shift from CIPS to IMEA as its requirements supplier and CIPS will sell additional power and energy to IMEA for resale to Greenup.

CIPS requests an effective date of August 1, 1997, and accordingly, requests that the Commission waive its notice requirements. Copies of this filing have been served on Greenup, IMEA and the Illinois Commerce Commission.

*Comment date:* November 5, 1997, in accordance with Standard Paragraph E at the end of this notice.

**Standard Paragraph**

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the

Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–28536 Filed 10–27–97; 8:45 am]

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## FEDERAL ENERGY REGULATORY COMMISSION

**[Docket No. ER97–3830–000, et al.]**

## Market Responsive Energy, Inc., et al. Electric Rate and Corporate Regulation Filings

October 20, 1997.

Take notice that the following filings have been made with the Commission:

### 1. Market Responsive Energy, Inc.

[Docket No. ER97–3830–000]

Take notice that on September 15, 1997, Market Responsive Energy, Inc. tendered for filing a Notice of Withdrawal of its July 23, 1997, filing in the above-referenced docket.

*Comment date:* October 30, 1997, in accordance with Standard Paragraph E at the end of this notice.

### 2. PJM Interconnection, L.L.C. Operating Agreement

[Docket No. ER97–4642–000]

Take notice that on September 16, 1997, the PJM Interconnection, L.L.C (PJM) filed on behalf of the Members of the LLC, membership applications of NorAm Energy Services, Inc. and NP Energy Inc. PJM requests an effective date of September 16, 1997.

*Comment date:* October 31, 1997, in accordance with Standard Paragraph E at the end of this notice.

### 3. IES Utilities Inc.

[Docket No. ER97–4792–000]

Take notice that on September 26, 1997, IES Utilities Inc. tendered for filing a Notice of Cancellation that the following service agreements with IES Utilities Inc. (IES) pursuant to its FERC Electric Tariff, Original Volume No. 1, were canceled:

SA55 City of Tipton, Iowa
SA60 Farmers Electric Coop/Kalona and the associated Peaking Power Contract
SA76 West Point Municipal Electric System and the associated Peaking Power Contract

In addition, effective the first day of January, 1997, the following service agreement with IES pursuant to its FERC Electric Tariff, Original Volume No. 6 will be executed: City of Tipton, Iowa.

Notice of the proposed cancellation and addition has been served upon the Iowa Department of Commerce.

*Comment date:* October 31, 1997, in accordance with Standard Paragraph E at the end of this notice.

### 4. Illinois Power Company

[Docket No. ER97–4793–000]

Take notice that on September 29, 1997, Illinois Power Company (Illinois Power) tendered for filing firm transmission agreements under which Tenneco Packaging, Inc. will take transmission service pursuant to its open access transmission tariff. The agreements are based on the Form of Service Agreement in Illinois Power's tariff.

Illinois Power has requested an effective date of September 5, 1996.

*Comment date:* October 31, 1997, in accordance with Standard Paragraph E at the end of this notice.

### 5. The Washington Water Power Company

[Docket No. ER97–4794–000]

Take notice that on September 30, 1997, The Washington Water Power Company (''WWP'') tendered for filing with the Federal Energy Regulatory Commission an executed Firm Point to Point Firm Service Agreement under WWP's Open Access Transmission Tariff, Second Revised Volume No. 8. WWP requests an effective date of October 1, 1997.

*Comment date:* October 31, 1997, in accordance with Standard Paragraph E at the end of this notice.

### 6. UtiliCorp United Inc.

[Docket No. ER97–4795–000]

Take notice that on September 30, 1997, UtiliCorp United Inc. (UtiliCorp) filed service agreements with Cinergy Services, Inc., for service under its short-term firm point-to-point open access service tariff for its operating divisions, Missouri Public Service, WestPlains Energy-Kansas and WestPlains Energy-Colorado.

*Comment date:* October 31, 1997, in accordance with Standard Paragraph E at the end of this notice.

### 7. Allegheny Power Service Corporation on behalf of Monongahela Power Company, The Potomac Edison Company, and West Penn Power Company (Allegheny Power)

[Docket No. ER97–4796–000]

Take notice that on September 30, 1997, Allegheny Power Service Corporation on behalf of Monongahela Power Company, The Potomac Edison Company and West Penn Power Company (Allegheny Power), filed Supplement No. 24 to add Strategic Energy Ltd., Tennessee Valley Authority and Western Resources to Allegheny Power Open Access Transmission Service Tariff which has been submitted for filing by the Federal Energy Regulatory Commission in Docket No. OA96–18–000. The proposed effective date under the Service Agreements is September 29, 1997.

*Comment date:* October 31, 1997, in accordance with Standard Paragraph E at the end of this notice.

### 8. Long Island Lighting Company

[Docket No. ER97–4797–000]

Take notice that on September 30, 1997, Long Island Lighting Company (LILCO) filed a Service Agreement for Non-Firm Point-to-Point Transmission Service between LILCO and The Energy Exchange Group (Transmission Customer).

The Service Agreement specifies that the Transmission Customer has agreed to the rates, terms and conditions of the LILCO open access transmission tariff filed on July 9, 1996, in Docket No. OA96–38–000.

LILCO requests waiver of the Commission's sixty (60) day notice requirements and an effective date of September 9, 1997, for the Service Agreement. LILCO has served copies of the filing on the New York State Public Service Commission and on the Transmission Customer.

*Comment date:* October 31, 1997, in accordance with Standard Paragraph E at the end of this notice.

### 9. Northeast Utilities Service Company

[Docket No. ER97–4798–000]

Take notice that Northeast Utilities Service Company (NUSCO), on September 30, 1997, tendered for filing, a Service Agreement with the Southern Company Services, Inc., under the NU System Companies' Sale for Resale, Tariff No. 7.

NUSCO states that a copy of this filing has been mailed to the Southern Company Services, Inc.

NUSCO requests that the Service Agreement become effective September 16, 1997.

*Comment date:* October 31, 1997, in accordance with Standard Paragraph E at the end of this notice.

**10. Northeast Utilities Service Company**

[Docket No. ER97–4800–000]

Take notice that Northeast Utilities Service Company (NUSCO), on September 30, 1997, tendered for filing, a Service Agreement with the Carolina Power & Light Company, under the NU System Companies' System Power Sales/Exchange Tariff No. 6.

NUSCO states that a copy of this filing has been mailed to the Carolina Power & Light Company.

NUSCO requests that the Service Agreement become effective September 17, 1997.

*Comment date:* October 31, 1997, in accordance with Standard Paragraph E at the end of this notice.

**11. Allegheny Power Service Corporation, on behalf of Monongahela Power Company, The Potomac Edison Company & West Penn Power Company (Allegheny Power)**

[Docket No. ER97–4801–000]

Take notice that on September 30, 1997, Allegheny Power Service Corporation on behalf of Monongahela Power Company, The Potomac Edison Company and West Penn Power Company (Allegheny Power) filed Supplement No. 32 to add two (2) new Customers to the Standard Generation Service Rate Schedule under which Allegheny Power offers standard generation and emergency service on an hourly, daily, weekly, monthly or yearly basis. Allegheny Power requests a waiver of notice requirements to make service available as of September 29, 1997, to Strategic Energy Ltd. and Tennessee Valley Authority.

Copies of the filing have been provided to the Public Utilities Commission of Ohio, the Pennsylvania Public Utility Commission, the Maryland Public Service Commission, the Virginia State Corporation Commission, the West Virginia Public Service Commission, and all parties of record.

*Comment date:* October 31, 1997, in accordance with Standard Paragraph E at the end of this notice.

**12. Toledo Edison Company**

[Docket No. ER97–4802–000]

Take notice that on September 30, 1997, Toledo Edison Company (''Toledo Edison'') tendered for filing an electric power service agreement for the sale of electricity under its FERC Electric Tariff, Original Volume No. 3, to LG&E Energy Marketing, Inc. Toledo Edison has requested waiver of the notice provisions of the Commission's regulations and any other applicable requirement in order to permit the service agreement to be made effective as of October 1, 1997.

*Comment date:* October 31, 1997, in accordance with Standard Paragraph E at the end of this notice.

**13. Entergy Services, Inc.**

[Docket No. ER97–4803–000]

Take notice that on September 30, 1997, Entergy Services, Inc. (''Entergy Services''), on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc. (collectively, the ''Entergy Operating Companies''), tendered for filing a Short-Term Market Rate Sales Agreement between Entergy Services, as agent for the Entergy Operating Companies, and Union Electric Company for the sale of power under Entergy Services' Rate Schedule SP.

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**14. Entergy Services, Inc.**

[Docket No. ER97–4804–000]

Take notice that on September 30, 1997, Entergy Services, Inc. (Entergy Services), on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc. (collectively, the Entergy Operating Companies), tendered for filing a Non-Firm Point-To-Point Transmission Service Agreement between Entergy Services, as agent for the Entergy Operating Companies, and AIG Trading Corporation.

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**15. Entergy Services, Inc.**

[Docket No. ER97–4805–000]

Take notice that on September 30, 1997, Entergy Services, Inc. (Entergy Services), on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc. (collectively, the Entergy Operating Companies), tendered for filing a Non-Firm Point-To-Point Transmission Service Agreement between Entergy Services, as agent for the Entergy Operating Companies, and Avista Energy, Inc.

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**16. Entergy Services, Inc.**

[Docket No. ER97–4806–000]

Take notice that on September 30, 1997, Entergy Services, Inc. (Entergy Services), on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc. (collectively, the Entergy Operating Companies), tendered for filing a Short-Term Firm Point-To-Point Transmission Service Agreement between Entergy Services, as agent for the Entergy Operating Companies, and Equitable Power Services Company.

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**17. Entergy Services, Inc.**

[Docket No. ER97–4807–000]

Take notice that on September 30, 1997, Entergy Services, Inc. (Entergy Services), on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc. (collectively, the Entergy Operating Companies), tendered for filing a Non-Firm Point-To-Point Transmission Service Agreement between Entergy Services, as agent for the Entergy Operating Companies and Duke Energy Trading and Marketing, L.L.C.

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**18. Entergy Services, Inc.**

[Docket No. ER97–4808–000]

Take notice that on September 30, 1997, Entergy Services, Inc. (Entergy Services), on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc. (collectively, the Entergy Operating Companies), tendered for filing a Short-Term Firm Point-To-Point Transmission Service Agreement between Entergy Services, as agent for the Entergy Operating Companies and Duke Energy Trading and Marketing, L.L.C.

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**19. Entergy Services, Inc.**

[Docket No. ER97–4809–000]

Take notice that on September 30, 1997, Entergy Services, Inc. (Entergy Services), on behalf of Entergy

Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc. (collectively, the Entergy Operating Companies), tendered for filing a Short-Term Firm Point-To-Point Transmission Service Agreement between Entergy Services, as agent for the Entergy Operating Companies and Avista Energy, Inc.

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**20. Entergy Services, Inc.**

[Docket No. ER97–4810–000]

Take notice that on September 30, 1997, Entergy Services, Inc. (Entergy Services), on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc. (collectively, the Entergy Operating Companies), tendered for filing a Non-Firm Point-To-Point Transmission Service Agreement between Entergy Services, as agent for the Entergy Operating Companies and Equitable Power Services Company.

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**21. Boston Edison Company**

[Docket No. ER97–4811–000]

Take notice that on September 30, 1997, Boston Edison Company (Boston Edison) tendered for filing a Standstill Agreement between itself and Commonwealth Electric Company (Commonwealth). The Standstill Agreement extends through November 30, 1997 the time in which Commonwealth may institute a legal challenge to the 1995 true-up bill under Boston Edison's FERC Rate Schedule No. 68, governing sales to Commonwealth from the Pilgrim Nuclear Station.

Boston Edison requests waiver of the Commission's notice requirement to allow the Standstill Agreement to become effective October 1, 1997.

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**22. Boston Edison Company**

[Docket No. ER97–4812–000]

Take notice that on September 30, 1997, Boston Edison Company (Boston Edison) tendered for filing a Standstill Agreement between itself and The Boylston Municipal Light Department, City of Holyoke Gas & Electric Department, Hudson Light and Power Department, Littleton Electric Light & Water Departments, Marblehead Municipal Light Department, Middleborough Gas and Electric Department, North Attleborough Electric Department, Peabody Municipal Light Plant, Shrewsbury's Electric Light Plant, Templeton Municipal Light Plant, Wakefield Municipal Light Department, West Boylston Municipal Lighting Plant, and Westfield Gas & Electric Light Department (Municipals). The Standstill Agreement extends through November 30, 1997, the time in which the Municipals may institute a legal challenge to the 1995 true-up bill under their respective contracts to purchase power from Boston Edison's Pilgrim Nuclear Station.

Boston Edison requests waiver of the Commission's notice requirement to allow the Standstill Agreement to become effective October 1, 1997.

The Standstill Agreement relates to the following Boston Edison FERC Rate Schedules:

(1) Supplement to Rate Schedule No. 77—Standstill Agreement with Boylston Municipal Light Department
(2) Supplement to Rate Schedule No. 79—Standstill Agreement with Holyoke Gas and Electric Department
(3) Supplement to Rate Schedule No. 81—Standstill Agreement with Westfield Gas and Electric Light Department
(4) Supplement to Rate Schedule No. 83—Standstill Agreement with Hudson Light and Power Department
(5) Supplement to Rate Schedule No. 85—Standstill Agreement with Littleton Electric Light and Water Department
(6) Supplement to Rate Schedule No. 87—Standstill Agreement with Marblehead Municipal Light Department
(7) Supplement to Rate Schedule No. 89—Standstill Agreement with North Attleborough Electric Department
(8) Supplement to Rate Schedule No. 91—Standstill Agreement with Peabody Municipal Light Plant
(9) Supplement to Rate Schedule No. 93—Standstill Agreement with Shrewsbury's Electric Light Plant
(10) Supplement to Rate Schedule No. 95—Standstill Agreement with Templeton Municipal Light Plant
(11) Supplement to Rate Schedule No. 97—Standstill Agreement with Wakefield Municipal Light Department
(12) Supplement to Rate Schedule No. 99—Standstill Agreement with West Boylston Municipal Lighting Plant
(13) Supplement to Rate Schedule No. 102—Standstill Agreement with Middle-borough Gas and Electric Department

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**23. Western Resources, Inc.**

[Docket No. ER97–4814–000]

Take notice that on September 30, 1997, Western Resources, Inc. tendered for filing five firm transmission agreements between Western Resources and Western Resources Generation Services. Western Resources states that the purpose of the agreements is to permit non-discriminatory access to the transmission facilities owned or controlled by Western Resources in accordance with Western Resources' open access transmission tariff on file with the Commission. The agreements are proposed to become effective September 12, 1997, September 16, 1997, September 18, 1997, September 25, 1997, and September 29, 1997, respectively.

Copies of the filing were served upon Western Resources Generation Services and the Kansas Corporation Commission.

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**24. Wisconsin Power and Light Co.**

[Docket No. ER97–4815–000]

Take notice that on September 30, 1997, Wisconsin Power and Light Company (WP&L) tendered for filing Form of Service Agreement for Firm Point-to-Point Transmission Service establishing Southern Energy Trading and Marketing, Inc. as a point-to-point transmission customer under the terms of WP&L's transmission tariff.

WP&L requests an effective date of September 1, 1997, and; accordingly, seeks waiver of the Commission's notice requirements. A copy of this filing has been served upon the Public Service Commission of Wisconsin.

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**25. Soyland Power Cooperative, Inc.**

[Docket No. ER97–4816–000]

Take notice that Soyland Power Cooperative, Inc. (Soyland), on September 30, 1997, tendered for filing proposed changes in its FERC Electric Service Tariff, Rate Schedule FERC Nos. 1, 2, 3, 4, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 19, 20, and 21.

The filing reflects a change in Soyland's Rate Schedule A formulary rate plus elimination of Riders LL and CP and institution of Rider I, to be effective January 1, 1998. No increase in revenues is contemplated. Copies of the

filing were served upon Soyland's Members and the Illinois Commerce Commission.

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**26. Cinergy Services, Inc., The Cincinnati Gas & Electric Company and PSI Energy, Inc.**

[Docket No. ER97–4817–000]

Take notice that on September 30, 1997, Cinergy Services, Inc. (Cinergy), on behalf of The Cincinnati Gas & Electric Company and PSI Energy, Inc., filed a partially executed Master Power Sales Contract between Cinergy and the Electric Utility Department of the City of Austin, Texas.

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**27. Northern States Power Company (Minnesota Company)**

[Docket No. ER97–4818–000]

Take notice that on September 30, 1997, Northern States Power Company (NSP) tendered Amendment No. 1 to the Municipal Interconnection and Interchange Agreement between NSP and the City of Melrose. NSP requests an effective date of October 1, 1997.

A copy of the filing was served upon each of the parties named in the Service List.

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**28. The Washington Water Power Company**

[Docket No. ER97–4819–000]

Take notice that on September 30, 1997, The Washington Water Power Company (''WWP'') tendered for filing with the Federal Energy Regulatory Commission pursuant to 18 CFR 35.13 an executed Interconnection and Operating Agreement between WWP and Clearwater Power Company. WWP requests an effective date of October 1, 1997.

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**29. Northern States Power Company (Minnesota Company)**

[Docket No. ER97–4820–000]

Take notice that on September 30, 1997, Northern States Power Company (NSP) tendered Amendment No. 1 to the Municipal Interconnection and Interchange Agreement between NSP and the City of Fairfax. NSP requests an effective date of October 1, 1997.

A copy of the filing was served upon each of the parties named in the Service List.

*Comment date:* November 3, 1997, in accordance with Standard Paragraph E at the end of this notice.

**Standard Paragraph:**

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–28537 Filed 10–27–97; 8:45 am]

BILLING CODE 6717–01–P

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Notice of Application Filed With the Commission

October 22, 1997.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Non-project use of project lands and non-project water withdrawal.

b. *Project No.:* 2413–034.

c. *Date Filed:* September 25, 1997.

d. *Applicant:* Georgia Power Company.

e. *Name of Project:* Wallace Dam Project.

f. *Location:* Oconee River, Altamaha River Basin, in Putnam, Morgan, Oconee, Oglethorpe, Greene, and Hancock Counties, Georgia.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C 791(a)–825(r).

h. *Applicant Contact:* Larry J. Wall, Georgia Power Company, 333 Piedmont Avenue N.E., Atlanta, Georgia 30308, (404) 526–2054.

i. *FERC Contact:* B. Peter Yarrington, (202) 219–2939.

j. *Comment Date:* December 11, 1997.

k. *Description of Project:* Licensee proposes to allow the city of Madison, Georgia to locate a water withdrawal facility within the project boundary. The facility will withdraw up to 4 million gallons of water a day from the project reservoir, for domestic consumption.

l. This notice also consists of the following standard paragraphs: B, C1, and D2.

B. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

C1. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

D2. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

**Lois D. Cashell,**

*Secretary.*

[FR Doc. 97–28462 Filed 10–27–97; 8:45 am]

BILLING CODE 6717–01–M

## FEDERAL MARITIME COMMISSION

### Sunshine Act Meeting

**AGENCY HOLDING THE MEETING:** Federal Maritime Commission.

**TIME AND DATE:** 5:00 a.m., October 23, 1997.

**PLACE:** 800 North Capitol Street, NW., Room 1000, Washington, D.C.

**STATUS:** Closed.

**MATTER(S) TO BE CONSIDERED:**

1. Docket No. 96–20—Port Restrictions and Requirements in the United States/Japan Trade.

**CONTACT PERSON FOR MORE INFORMATION:** Joseph C. Polking, Secretary, (202) 523–5725.

**Joseph C. Polking,**

*Secretary.*

[FR Doc. 97–28617 Filed 10–24–97; 8:45 am]

BILLING CODE 6730–01–M

## FEDERAL RESERVE SYSTEM

### Sunshine Act Meeting

**AGENCY HOLDING THE MEETING:** Board of Governors of the Federal Reserve System.

**TIME AND DATE:** 11:00 a.m., Monday, November 3, 1997.

**PLACE:** Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

**STATUS:** Closed.

**MATTERS TO BE CONSIDERED:**

1. Status Report of the Committee on the Federal Reserve in the Payments Mechanism (Alternative Roles for the Federal Reserve in the Retail Payments System). (This item was originally announced for a closed meeting on October 20, 1997.)

2. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

3. Any items carried forward from a previously announced meeting.

**CONTACT PERSON FOR MORE INFORMATION:** Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: October 24, 1997.

**Jennifer J. Johnson,**

*Deputy Secretary of the Board.*

[FR Doc. 97–28682 Filed 10–24–97; 2:45 pm]

BILLING CODE 6210–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### Office of Inspector General; Statement of Organization, Functions and Delegations of Authority

This notice amends Part A (Office of the Secretary) of the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (HHS) to reflect recent changes in Chapter AF, Office of Inspector General (OIG). Chapter AF was published in its entirety on June 5, 1997 (62 FR 30859).

The statement of organization, functions and delegations of authority reflects the original transfer of the statutory basis for the Office of Inspector General from Pub. L. 94–505 to Pub. L. 95–452 (and made under the Inspector General Act Amendments of 1988, Pub. L. 100–504), and conforms to and carries out the statutory requirements for operating the Office of Inspector General. A number of revisions have been made to reflect the reassignment of functions exercised by the Office of Enforcement and Compliance to two other components. As a result, the Office of Investigations will now be responsible for the development and processing of all program exclusion actions. The Office of Counsel to the Inspector General will now be responsible for final decisions regarding administrative sanctions, including program exclusions and civil money penalties (CMPs), and for developing corporate integrity and model compliance programs, as well as the monitoring of corporate integrity agreements. These organizational changes have been made in an effort to assist the Office of Inspector General in accomplishing its mission with greater efficiency and effectiveness.

As amended, Chapter AF now reads as follows:

*Section AF.00, Office of Inspector General (OIG)—Mission.*

This organization was established by law as an independent and objective oversight unit of the Department to carry out the mission of promoting economy, efficiency and effectiveness through the elimination of waste, abuse and fraud. In furtherance of this mission, the organization engages in a number of activities:

A. Conducting and supervising audits, investigations, inspections and evaluations relating to HHS programs and operations.

B. Identifying systemic weaknesses giving rise to opportunities for fraud and abuse in HHS programs and operations and making recommendations to prevent their recurrence.

C. Leading and coordinating activities to prevent and detect fraud and abuse in HHS programs and operations.

D. Detecting wrongdoers and abusers of HHS programs and beneficiaries so appropriate remedies may be brought to bear.

E. Keeping the Secretary and the Congress fully and currently informed about problems and deficiencies in the administration of such programs and operations and about the need for and progress of corrective action, including imposing sanctions against providers of health care under Medicare and Medicaid who commit certain prohibited acts.

In support of its mission, the Office of Inspector General carries out and maintains an internal quality assurance system and a peer review system with other Offices of Inspectors General, that include periodic quality assessment studies and quality control reviews, to provide reasonable assurance that applicable laws, regulations, policies, procedures, standards and other requirements are followed; are effective; and are functioning as intended in OIG operations.

*Section AF.10, Office of Inspector General—Organization*

There is at the head of the OIG a statutory Inspector General, appointed by the President and confirmed by the Senate. The Office of Inspector General consists of six organizational units:

A. Immediate Office of the Inspector General (AFA).

B. Office of Management and Policy (AFC).

C. Office of Evaluation and Inspections (AFE).

D. Office of Counsel to the Inspector General (AFG).

E. Office of Audit Services (AFH).

F. Office of Investigations (AFJ).

*Section AF.20, Office of Inspector General—Functions*

The component sections which follow describe the specific functions of the organization.

*Section AFA.00, Immediate Office of the Inspector General (IOIG)—Mission*

The Inspector General is directly responsible for meeting the statutory mission of the OIG as a whole and for promoting effective OIG internal quality assurance systems, including quality assessment studies and quality control

reviews of OIG processes and products. The Office of Inspector General also plans, conducts and participates in a variety of inter-agency cooperative projects and undertakings relating to fraud and abuse activities with the Department of Justice (DOJ), the Health Care Financing Administration (HCFA) and other governmental agencies.

*Section AFA.10, Immediate Office of the Inspector General—Organization*

The Immediate Office is comprised of the Inspector General, the Principal Deputy Inspector General, and an immediate staff.

*Section AFA.20, Immediate Office of the Inspector General—Functions*

As the senior official of the organization, the Inspector General supervises the Chief Counsel to the Inspector General and the Deputy Inspectors General who head the major OIG components. The Inspector General is appointed by the President, with the advice and consent of the Senate, and reports to and is under the general supervision of the Secretary or, to the extent such authority is delegated, the Deputy Secretary, but does not report to and is not subject to supervision by any other officer in the Department. In keeping with the independence intended in the statutory basis for the OIG and its mission, the Inspector General assumes and exercises, through line management, all functional authorities related to the administration and management of the OIG and all mission related authorities stated or implied in the law or delegated directly from the Secretary.

The Inspector General provides executive leadership to the organization and exercises general supervision over the personnel and functions of its major components. The Inspector General determines the budget needs of the OIG, sets OIG policies and priorities, oversees OIG operations and provides reports to the Secretary and the Congress. In this capacity the Inspector General is empowered under the law with general personnel authority, e.g., selection, promotion, assignment of employees, including members of the senior executive service. The Inspector General delegates related authorities as appropriate.

The Principal Deputy Inspector General assists the Inspector General in the management of the OIG, and during the absence of the Inspector General, acts as the Inspector General.

*Section AFC.00, Office of Management and Policy (OMP)—Mission*

This office is responsible for the reporting and legislative and regulatory review functions required in the law; for formulating and executing the OIG budget; for managing external affairs; and for establishing functional policies for the general management of the OIG. In support of its mission, the office carries out and maintains an internal quality assurance system. The system includes quality assessment studies and quality control reviews of OMP processes and products to ensure that policies and procedures are followed effectively and function as intended.

*Section AFC.10, Office of Management and Policy—Organization*

This office is directed by the Deputy Inspector General for Management and Policy, and comprises the Deputy Inspector General for OMP and an immediate staff.

*Section AFC.20, Office of Management and Policy—Functions*

Through the Deputy Inspector General for Management and Policy:

A. The office conducts and coordinates OIG reviews of existing and proposed legislation and regulations related to HHS programs and operations to identify their impact on economy and efficiency and their potential for fraud and abuse. It serves as contact for the press and electronic media and serves as OIG congressional liaison. The office prepares or coordinates congressional testimony and confers with officials in the Office of the Secretary staff divisions on congressional relations, legislation and public affairs. It develops and publishes OIG newsletters, recruitment brochures and other issuances to announce and promote OIG activities and accomplishments.

B. The office coordinates the development of the OIG long-range strategic plan. It compiles the Semiannual and other legislatively-mandated reports to the Congress and operates the Executive Secretariat. It formulates and oversees the execution of the OIG budget and confers with the Office of the Secretary, the Office of Management and Budget and the Congress on budget issues. It issues quarterly grants to States for Medicaid fraud control units. It conducts management studies and analyses and establishes and coordinates general management policies for the OIG and publishes those policies in the OIG Administrative Manual. It serves as OIG liaison to the Office of the Secretary for personnel issues and other administrative policies and practices, and on equal employment opportunity and other civil rights matters. It coordinates internal control reviews for the OIG.

C. The office is responsible for OIG information resources management (IRM), as defined by the Paperwork Reduction Act, OMB Circular A–130, the Federal Information Resources Management regulations, the Computer Security Act of 1987, HHS IRM Circulars, and by related guidance. The office also provides information technology support to the OIG through management of its local area networks nationwide, provision of headquarters computer end-user support, and support of OIG information systems as required. Through this office, the Deputy Inspector General for Management and Policy serves as the OIG Chief Information Officer.

*Section AFE.00, Office of Evaluation and Inspections (OEI)—Mission*

The Office of Evaluation and Inspections is responsible for conducting inspections of HHS programs, operations and processes to identify vulnerabilities, to prevent and detect fraud, waste and abuse, and to promote economy, efficiency and effectiveness in HHS programs and operations.

*Section AFE.10, Office of Evaluation and Inspections—Organization*

This office is directed by the Deputy Inspector General for Evaluation and Inspections, and comprises the Immediate Office, including the Deputy Inspector General for OEI and an immediate staff, and eight regional offices.

*Section AFE.20, Office of Evaluation and Inspections—Functions*

The office is responsible for carrying out inspections supporting the OIG mission. The Deputy Inspector General provides general supervision to the OEI immediate office staff and supervises the Regional Inspectors General for Evaluation and Inspections who carry out OEI's mission and activities in assigned geographic areas. The Immediate Office carries out OEI's mission in headquarters.

A. The immediate office develops OEI's evaluation and inspections policies, procedures and standards. It manages OEI's human and financial resources. It develops and monitors OEI's management information systems. It conducts management reviews within the HHS/OIG and for other OIG's upon request. The office carries out and maintains an internal quality assurance

system. The system includes quality assessment studies and quality control reviews of OEI processes and products to ensure that policies and procedures are effective; are followed; and are functioning as intended.

B. The immediate office manages OEI's work planning process, and develops and reviews legislative, regulatory and program proposals to reduce vulnerabilities to fraud, waste and mismanagement. It develops evaluation techniques and coordinates projects with other OIG and departmental components. It provides programmatic expertise and information on new programs, procedures, regulations and statutes to OEI regional offices. It maintains liaison with other components in the Department, follows up on implementation of corrective action recommendations, evaluates the actions taken to resolve problems and vulnerabilities identified, and provides additional data or corrective action options, where appropriate.

C. The immediate office provides statistical and data base advice and services for inspections conducted by the regional offices. It carries out analyses of large data bases to identify potential areas of fraud and abuse, and provides technical assistance to the regional offices for these purposes. It operates a toll-free hotline for the OIG to permit individuals to call in suspected fraud or waste, refers the calls for appropriate action by HHS agencies or other OIG components, and analyzes the body of calls to identify trends and patterns of fraud and abuse needing attention.

D. The regional offices carry out OEI's mission in the field. The regional offices evaluate HHS programs and produce the results in inspection reports. They conduct data and trend analyses of major HHS initiatives to determine the effects of current policies and practices on program efficiency and effectiveness. They recommend changes in program policies, regulations and laws to improve efficiency and effectiveness, and to prevent fraud, abuse, waste and mismanagement. They analyze existing policies to evaluate options for future policy, regulatory and legislative improvements.

*Section AFG.00, Office of Counsel to the Inspector General (OCIG)—Mission*

The Office of Counsel to the Inspector General (OCIG) is responsible for providing all legal services and advice to the Inspector General, Principal Deputy Inspector General and all the subordinate components of the Office of Inspector General, in connection with OIG operations and administration, OIG fraud and abuse enforcement activities, and OIG activities designed to promote efficiency and economy in the Department's programs and operations. The OCIG is also responsible for imposing and litigating CMP and program exclusion cases within the jurisdiction of the OIG, for the coordination and disposition of False Claims Act *qui tam* and criminal, civil and administrative matters, and for the resolution of voluntary disclosure and program compliance activities. The OCIG develops models for corporate integrity, compliance and enforcement programs; monitors ongoing compliance; and promotes industry awareness of corporate integrity models.

*Section AFG.10, Office of Counsel to the Inspector General—Organization*

The office is directed by the Chief Counsel to the Inspector General, and the Assistant Inspector General for Legal Affairs. The office is comprised of the following components:

A. Advice.
B. Civil Recoveries.
C. Administrative Litigation.
D. Industry Guidance.

*Section AFG.20, Office of Counsel to the Inspector General—Functions*

A. Advice

This office provides legal advice to the various components of the OIG on legal issues that arise in the exercise of the OIG's responsibilities under the Inspector General Act of 1978. Such issues include the scope and exercise of the Inspector General's authorities and responsibilities; investigative techniques and procedures (including criminal procedure); the sufficiency and impact of legislative proposals affecting the OIG; and the conduct and resolution of investigations, audits and inspections. The office evaluates the legal sufficiency of OIG recommendations and develops formal legal opinions to support those recommendations. When appropriate, the office coordinates formal legal opinions with the HHS Office of the General Counsel. The office provides legal advice on OIG internal administration and operations, including appropriations, delegations of authority, ethics, OIG regulations, personnel matters, the disclosure of information under the Freedom of Information Act and the safeguarding of information under the Privacy Act. The office is responsible for conducting and coordinating litigation activities on personnel and Equal Employment Opportunity matters and Federal tort actions involving OIG employees. The office is responsible for the clearance and enforcement of subpoenas issued by the OIG, and defends the OIG in litigation matters as necessary.

B. Civil Recoveries

This office oversees all False Claims Act cases, including *qui tam* cases, and handles final sign-off on False Claims Act settlements for the Department, including the amount of restitution and resolution of the CMP and program exclusion authorities that have been delegated to the OIG. It coordinates DOJ and U.S. Attorney's offices resource requests, participates in settlement negotiations and provides litigation support. Where necessary, the office litigates appeals of program exclusions imposed in such global cases before the Department Appeals Board (DAB) and assists DOJ in handling any subsequent appeals of such cases to the Federal courts. The office coordinates and resolves all voluntary disclosure cases through: (1) Liaison activities with DOJ and the U.S. Attorney's office; (2) the disclosure verification efforts of OAS and OI; and (3) final disposition and sign-off of the matter. The office, in coordination with other OIG components, develops both the standards governing the use of program exclusion authorities, and the criteria for evaluating whether to impose program exclusions against health care providers. The office is responsible for developing and maintaining a comprehensive and coordinated data base on all settled and pending False Claims Act and CMP cases under its authority.

The Civil Recoveries Branch also develops and monitors corporate and provider integrity plans adopted as part of settlement agreements, and develops audit and investigative review standards for monitoring such plans in cooperation and coordination with other OIG components. The office resolves breaches of integrity plans through the development of corrective action plans, on-site reviews, and through the imposition of sanctions. It serves to increase industry awareness of corporate compliance integrity issues by promoting voluntary adoption of corporate compliance plans through speeches, articles, visits and other liaison activities with governmental and private sector groups, as well as developing model or best practice recommendations.

C. Administrative Litigation

This office is responsible for determining whether to impose administrative sanctions, including CMPs within the jurisdiction of the OIG,

assessments and program exclusions (with the exception of those handled by the Civil Recoveries Branch). It effectuates all such health care mandatory and permissive exclusions under the Social Security Act, and decides on waiver requests and requests for reinstatement. The office participates in developing standards governing the imposition of these exclusion authorities. The office coordinates with the Public Health Service and DOJ to effectuate repayment agreements with those excluded individuals who have defaulted on HEAL loans. The office litigates appeals of program exclusions before the DAB and assists DOJ in handling any subsequent appeals of such cases to the Federal courts.

The office reviews all cases referred by HCFA under the patient anti-dumping authority of the Social Security Act, and resolves the liability for CMPs and program exclusions for hospitals and physicians. Where appropriate, the office imposes and litigates CMPs and program exclusions with respect to hospitals and physicians for violations of the patient anti-dumping statute.

The office imposes and litigates CMPs and assessments under the CMP law, and ensures that all monetary recoveries are promptly and accurately reported to the appropriate OIG data base. It represents the OIG in coordinating all CMP actions initiated by other Federal health care programs that are authorized to prosecute health care providers. The office provides guidance and monitors all actions in this area until completion of these actions.

The Administrative Litigation Branch also has primary responsibility for developing and promulgating all OIG regulations for codification into the Code of Federal Regulations, all OIG-related **Federal Register** notices, and the review and drafting of legislative proposals relating to fraud and abuse enforcement activities.

D. Industry Guidance

This office is responsible for drafting and issuing advisory opinions to the health care industry and members of the public on whether an activity (or proposed activity) would constitute grounds for the imposition of a sanction under the anti-kickback statute, the CMP law or the program exclusion authorities, and on other issues pertaining to the anti-kickback statute. The office develops and updates procedures for the submission of requests for advisory opinions and for determining the fees that will be imposed. The office solicits and responds to proposals for new regulatory safe harbors to the anti-kickback statute, modifications to existing safe harbors, and new fraud alerts. The office consults with, and obtains the concurrence of, DOJ on all proposed advisory opinions and safe harbors before issuance or publication. The office provides legal advice to the various components of the OIG, other offices of the Department, and DOJ concerning matters involving the interpretation of the anti-kickback statute and other legal authorities, and assists those components or offices in analyzing the applicability of the anti-kickback statute to various practices or activities under review.

*Section AFH.00, Office of Audit Services (OAS)—Mission*

The Office of Audit Services provides policy direction for and conducts and oversees comprehensive audits of HHS programs, operations, grantees and contractors, following generally accepted Government auditing standards (GAGAS), the Single Audit Act of 1984, applicable Office of Management and Budget (OMB) circulars and other legal, regulatory and administrative requirements. This includes investigative audit work performed in conjunction with other OIG components, directed toward the prosecution of both civil and criminal cases of program abuse. It maintains an internal quality assurance system, including periodic quality assessment studies and quality control reviews, to provide reasonable assurance that applicable laws, regulations, policies, procedures, standards and other requirements are followed in all audit activities performed by, or on behalf of, the Department. In furtherance of this mission, the organization engages in a number of activities:

A. The office coordinates and confers with officials of the central Federal management agencies (OMB, the General Accounting Office (GAO), the Office of Personnel Management (OPM) and the Department of the Treasury) on audit matters involving HHS programs and operations. It provides technical assistance to Federal, State and local investigative offices on matters concerning the operation of the Department's programs. It participates in interagency efforts implementing OMB Circulars A–128 and A–110, which call for use of the single audit concept for most external audits. It performs audits of activities administered by other Federal departments, following the system of audit cognizance administered by OMB. It participates in the President's Council on Integrity and Efficiency (PCIE) initiatives and other Government-wide projects. It works with other OIG components on special assignments and projects. It responds to congressional oversight interests related to audit matters in the Department.

B. The Office of Audit Services helps HHS operating divisions and the Office of the Secretary staff divisions to develop policies to manage grants and procurements and policies to establish indirect cost rates. It performs pre-award audits of grant or contract proposals to determine the financial capability of the grantees or contractors and conducts post-award audits.

C. The office reviews legislative, regulatory and policy proposals for audit implications. It recommends improvements in the accountability and integrity features of legislation, regulations and policy. It prepares reports of audits and special studies for the Secretary, heads of HHS operating divisions, Regional Directors and others. It gathers data on unresolved audit findings for the statutorily required Semiannual Reports to the Congress and for the Deputy Secretary as Chairman of the Audit Resolution Council. It conducts follow-up examinations and special analyses of actions taken on previously reported audit findings and recommendations to ensure completeness and propriety.

D. The office decides when audits can or may be performed by audit organizations outside the Department, including those by other Federal or nonfederal governmental agencies, contractors, or public accounting firms. It assures that any audit performed by non-OIG auditors complies with the Government auditing standards established by the Comptroller General of the United States. It evaluates audits performed for the Department by outside organizations. It coordinates the development of the OIG Annual Work Plan and produces the Red Book—a summary of significant monetary recommendations not yet implemented.

E. The office serves as the focal point for all financial audit activity within the Department and provides the primary liaison conduit between the OIG and departmental management. The office provides overall leadership and direction in carrying out the responsibilities mandated under the Chief Financial Officers Act relating to financial statement audits.

*Section AFH.10, Office of Audit Services—Organization*

The Office of Audit Services comprises the following components:

A. Immediate Office.

B. Audit Operations and Financial Statement Activities.

C. Health Care Financing Audits.

D. Administrations of Children, Family and Aging Audits.

E. Public Health Audits.

*Section AFH.20, Office of Audit Services—Functions*

A. Immediate Office of the Deputy Inspector General for Audit Services

This office is directed by the Deputy Inspector General for Audit Services who carries out the functions designated in the law for the position, Assistant Inspector General for Auditing. The Deputy Inspector General for Audit Services is responsible to the Inspector General for carrying out OIG's audit mission and supervises the Assistant Inspectors General heading OAS offices described below.

The Immediate Office manages the human and financial resources of the Office of Audit Services including developing staffing allocation plans and issuing policy for, coordinating and monitoring all budget, staffing, recruiting and training activities of the office. Included in this is the responsibility to track court ordered or agreed-to costs of audits recouped from health care providers found to have violated Medicare fraud and abuse program provisions. It maintains a professional development program for Office of Audit Services staff which meets the requirements of Government auditing standards. The office provides liaison with the General Accounting Office. It reviews all replies to GAO reports to ensure they are responsive, properly coordinated and representative of HHS policy and advises the Secretary and other officials about significant findings.

B. Audit Operations and Financial Statement Activities

This office is directed by the Assistant Inspector General for Audit Operations and Financial Statement Activities. In addition to directing this office, the Assistant Inspector General supervises the eight Regional Inspectors General for Audit Services. The office's principal functions include providing direction and oversight to OAS through its work planning and quality assurance activities; the direct-line responsibility for audits of financial statements and financial related audits, including internal audits of functional areas within the Department; and directing field audit operations.

1. The office serves as the focal point for all financial statement and financial related audit activity within the Department and serves as the primary liaison conduit between the OIG and departmental management.

2. The office operates an internal quality assurance system that provides reasonable assurance that applicable laws, regulations, policies, procedures, standards and other requirements are followed in all audit activities performed by, or on behalf of, the Department.

3. The office evaluates audit work, including performing quality control reviews of audit reports, and develops and monitors audit work plans. It develops audit policy, procedures, standards, criteria and instructions for all audit activities performed by, on behalf of, or conforming with departmental programs, grants, contracts or operations in accordance with GAGAS and other legal, regulatory and administrative requirements.

4. The office tracks, monitors and reports on audit resolution and follow-up in accordance with OMB Circular A–50.

5. The office provides oversight for audits of governments, universities and nonprofit organizations conducted by nonfederal auditors and those under contract with the OIG (external audit resources).

6. The office coordinates with the other OIG components in developing the semiannual report to Congress.

C. Health Care Financing Audits

This office is directed by the Assistant Inspector General for Health Care Financing Audits. The office conducts programmatic and fraud and abuse oriented audits of HCFA program operations and oversees nationwide the audits of the Medicare and Medicaid programs, their contractors, and providers of services and products. It maintains an internal quality assurance system, including periodic quality control reviews, to provide reasonable assurance that applicable laws, regulations, policies, procedures, standards and other requirements are followed in all HCFA audit activities performed by, or on behalf of, the Department.

D. Administrations of Children, Family and Aging Audits

This office is directed by the Assistant Inspector General for Administrations of Children, Family and Aging Audits. The office conducts and oversees audits of the operations and programs of the Administration for Children and Families and the Administration on Aging, as well as statewide cost allocation plans. It maintains an internal quality assurance system, including periodic quality control reviews, to provide reasonable assurance that applicable laws, regulations, policies, procedures, standards and other requirements are followed in its audit activities.

E. Public Health Audits

This office is directed by the Assistant Inspector General for Public Health Audits. The office conducts and oversees audits of the programs and activities of the public health related agencies, including the Food and Drug Administration; the National Institutes of Health; the Health Resources and Services Administration; the Substance Abuse and Mental Health Services Administration; the Centers for Disease Control and Prevention; the Agency for Toxic Substances and Disease Registry; the Indian Health Service and the Surgeon General, as well as those colleges, universities and nonprofit organizations that receive research grants from the Federal Government. It maintains an internal quality assurance system, including periodic quality control reviews, to provide reasonable assurance that applicable laws, regulations, policies, procedures, standards and other requirements are followed in all public health related audit activities performed by, or on behalf of, the Department.

*Section AFJ.00, Office of Investigations (OI)—Mission*

The Office of Investigations is responsible for conducting and coordinating investigative activities related to fraud, waste, abuse and mismanagement in HHS programs and operations, including wrongdoing by applicants, grantees, or contractors, or by HHS employees in the performance of their official duties. It serves as OIG liaison to DOJ on all matters relating to investigations of HHS programs and personnel, and reports to the Attorney General when the OIG has reasonable grounds to believe Federal criminal law has been violated. The office serves as a liaison with HCFA, State licensing boards and other outside organizations and entities with regard to exclusion, compliance and enforcement activities. It works with other investigative agencies and organizations on special projects and assignments. In support of its mission, the office carries out and maintains an internal quality assurance system. The system includes quality assessment studies and quality control reviews of OI processes and products to ensure that policies and procedures are followed effectively, and are functioning as intended.

*Section AFJ.10, Office of Investigations—Organization*

The Office of Investigations comprises the following components:

A. Immediate Office.

B. Criminal Investigations.

C. Investigations Policy and Oversight.

*Section AFJ.20, Office of Investigations —Functions*

A. Immediate Office of the Deputy Inspector General for Investigations

This office is directed by the Deputy Inspector General for Investigations who is responsible for the functions designated in the law for the position, Assistant Inspector General for Investigations. The Deputy Inspector General for Investigations supervises the Assistant Inspector General and Division Director who head the OI offices described below.

The Deputy Inspector General for Investigations is responsible to the Inspector General for carrying out the investigative mission of the OIG and for leading and providing general supervision to the OIG investigative component. The Immediate Office coordinates quality assurance studies to ensure that applicable laws, regulations, policies, procedures, standards and other requirements are followed in all investigative activities performed by, or on behalf of, the Department.

B. Criminal Investigations

This office is directed by the Assistant Inspector General for Criminal Investigations who supervises a headquarters policy and review staff and the Regional Inspectors General for Investigations who carry out investigative activities in their assigned geographic areas.

1. The headquarters staff assists the Deputy Inspector General for Investigations to establish investigative priorities, to evaluate the progress of investigations, and to report to the Inspector General on the effectiveness of investigative efforts. It develops and implements investigative techniques, programs, guidelines and policies. It provides programmatic expertise and issues information on new programs, procedures, regulations and statutes. It directs and coordinates the investigative field offices.

2. The headquarters staff reviews completed reports of investigations to ensure accuracy and compliance with guidelines. It issues the reports to pertinent agencies, management officials and the Secretary and recommends appropriate debarment actions, administrative sanctions, CMPs and other civil actions, or prosecution under criminal law. It identifies systemic and programmatic vulnerabilities in the Department's operations and makes recommendations for change to the appropriate managers.

3. The staff provides for the personal protection of the Secretary.

4. The field offices conduct investigations of allegations of fraud, waste, abuse, mismanagement and violations of standards of conduct and other investigative matters within the jurisdiction of the OIG. They coordinate investigations and confer with HHS operating divisions, staff divisions, OIG counterparts and other investigative and law enforcement agencies. They prepare investigative and management improvement reports.

5. The office develops all health care mandatory and permissive program exclusions, and ensures enforcement of exclusions imposed through liaison with HCFA, DOJ and other governmental and private sector entities. It is responsible for developing, improving and maintaining a comprehensive and coordinated OIG data base on all OIG exclusion actions, and promptly and accurately reports all exclusion actions within its authority to the data base. It informs appropriate regulatory agencies, health care providers and the general public of all OIG exclusion actions, and is responsible for improving public access to information on these exclusion actions to ensure that excluded individuals and entities are effectively barred from program participation.

C. Investigations Policy and Oversight

This office is directed by the Division Director for Investigations Policy and Oversight who leads outreach activities to State and local investigative agencies, and the general management functions of the Office of Investigations.

1. The office oversees State Medicaid fraud control units and is responsible for certifying and recertifying these units and for auditing their Federal funding. The office provides pertinent information from HHS records to assist Federal, State and local investigative agencies to detect, investigate and prosecute fraud.

2. The office maintains an automated data and management information system used by all OI managers and investigators. It provides technical expertise on computer applications for investigations and coordinates and approves investigative computer matches with other agencies.

3. The office develops general management policy for the OI. It develops and issues instructional media on detecting wrongdoing and on investigating and processing cases. The office reviews proposed legislation, regulations, policies and procedures to identify vulnerabilities and recommends modification where appropriate. It reviews investigative files in response to Privacy and Freedom of Information Act requests, and serves as OIG liaison to the Office of the Secretary for Freedom of Information and Privacy Act requests. It plans, develops, implements and evaluates all levels of employee training for investigations, management, support skills and other functions. It coordinates general management processes, e.g., compiles reports on the budget, on awards and on other personnel matters for OI as a whole; implements policies and procedures published in the OIG Administrative Manual; and processes procurement requests and other service related actions. It oversees a law enforcement techniques and equipment program.

Dated: October 6, 1997.

**June Gibbs Brown,**

*Inspector General.*

[FR Doc. 97–28541 Filed 10–27–97; 8:45 am]

ILLING CODE 4150–04–P

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

### Notice of Meeting

The Agency for Toxic Substances and Disease Registry announces the following meeting.

*Name:* Expert Workshop ı3 Regarding Medical Monitoring in Bunker Hill, Idaho.

*Times and Dates:* 8 a.m.–5 p.m., November 5, 1997; 8 a.m.–5 p.m., November 6, 1997.

*Place:* Elk's Temple #1841, 202½ McKinley Avenue, Kellogg, Idaho 83837, telephone 208/786–3901.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

*Purpose:* The Agency for Toxic Substances and Disease Registry (ATSDR) is considering the appropriateness of medical monitoring for populations who lived around the Bunker Hill former lead smelting facility (the Bunker Hill Superfund Site) in the Silver Valley of Idaho at a time of excess exposures of public health significance. As part of this consideration process, ATSDR is convening a series of workshops to examine the appropriateness and feasibility of a medical monitoring program.

The purpose of the medical monitoring program is to provide a public health service to communities affected by exposures to hazardous substances by screening target populations at significant risk of a specific

health effect or outcome, identifying individuals in need of further diagnosis or treatment, and arranging for appropriate referrals.

Section 104(i)(9) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended (42 U.S.C. 9604(i)(9)), provides for the Administrator, ATSDR to initiate a health surveillance program for populations at significantly increased risk of adverse health effects as a result of exposure to hazardous substances released from a facility. A program included under health surveillance is referred to as ''medical monitoring or screening'' by ATSDR and is defined in the legislation as ''the periodic medical testing to screen people at significant increased risk for disease.''

ATSDR has established criteria to determine when medical monitoring is an appropriate health activity and the requirements for establishing a medical monitoring program at a site. The legislation also states that a mechanism to refer people for treatment should be included in the program. This statutory provision does not authorize ATSDR to provide medical treatment. Medical monitoring is a community service, not a health study.

ATSDR is convening three expert workshops to assist in the evaluation of a medical monitoring program at the Bunker Hill site. If a program is deemed appropriate, the agency will develop a medical monitoring plan for the target population(s). The first workshop, considering the first four ATSDR medical monitoring criteria, took place on August 19–20, 1997. The second workshop, which took place on September 23–24, 1997, examined more closely the health outcomes recommended by the first workshop and considered screening tests and protocols appropriate to a medical monitoring program. This document gives notice of the third workshop.

*Matters to be Considered:* The third workshop will reconvene the first workshop's participants and other experts as needed to:

- Consider the application of the final three medical monitoring criteria as developed by ATSDR, and review ATSDR's application of these criteria, to the Bunker Hill site
- Provide individual recommendations and guidance on issues of science and public health practice related to program implementation
- Provide individual expertise and guidance in conducting a medical outcome and decision analysis to evaluate the public health benefits and risks of a medical monitoring program related to the Bunker Hill site.

The experts will use information from the first and second workshops and other relevant data to make individual recommendations and answer questions related to key issues including the logistics, program infrastructure, benefit analysis, and other aspects of the medical monitoring system criteria for each candidate health outcome.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Vivian Rush, M.D., Medical Officer, ATSDR, Division of Health Education and Promotion, 1600 Clifton Road, NE, M/S E–33, Atlanta, Georgia 30333, telephone 404/639–5080, or Gregory Thomas, Senior Regional Representative, ATSDR Region X, telephone 206/553–2113.

Dated: October 22, 1997.

**Julia M. Fuller,**

*Acting Director, Management Analysis and Services Office Centers for Disease Control and Prevention (CDC).*

[FR Doc. 97–28483 Filed 10–27–97; 8:45 am]

BILLING CODE 4163–70–P

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

**[ATSDR–128]**

### Availability of Draft Toxicological Profiles

**AGENCY:** Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

**ACTION:** Notice of availability.

**SUMMARY:** The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA) (42 U.S.C. 9604(i)(3)) directs the Administrator of ATSDR to prepare toxicological profiles of priority hazardous substances and to revise and publish each updated toxicological profile as necessary. This notice announces the availability of ten updated drafts and three new draft toxicological profiles, comprising the 11th set, prepared by ATSDR for review and comment.

**DATES:** To ensure consideration, comments on these draft toxicological profiles must be received on or before February 17, 1998. Comments received after the close of the public comment period will be considered at the discretion of ATSDR based upon what is deemed to be in the best interest of the general public.

**ADDRESSES:** Requests for copies of the draft toxicological profiles or comments regarding the draft toxicological profiles should be sent to the attention of Ms. Loretta Norman, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

Requests for the draft toxicological profiles must be in writing, and must specifically identify the hazardous substance(s) profile(s) that you wish to receive. ATSDR reserves the right to provide only one copy of each profile requested, free of charge. In case of extended distribution delays, requestors will be notified.

Written comments and other data submitted in response to this notice and the draft toxicological profiles should bear the docket control number ATSDR–128. Send one copy of all comments and three copies of all supporting documents to the Division of Toxicology at the above address by the end of the comment period. Because all public comments regarding ATSDR toxicological profiles are available for public inspection after the profile is published in final, no confidential business information should be submitted in response to this notice.

**FOR FURTHER INFORMATION CONTACT:** Ms. Loretta Norman, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639–6322.

**SUPPLEMENTARY INFORMATION:** The Superfund Amendments and Reauthorization Act (SARA) (Pub. L. 99–499) amends the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) (42 U.S.C. 9601 *et seq.*) by establishing certain responsibilities for the ATSDR and the Environmental Protection Agency (EPA) with regard to hazardous substances which are most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these statutory provisions is that the Administrator of ATSDR prepare toxicological profiles for substances included on the priority lists of hazardous substances. These lists identified 275 hazardous substances that ATSDR and EPA determined pose the most significant potential threat to human health. The availability of the revised priority list of 275 hazardous substances was announced in the **Federal Register** on April 29, 1996 (61 FR 18744 ). For prior versions of the list of substances see **Federal Register** notices dated April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); and February 28, 1994 (59 FR 9486). CERCLA also requires ATSDR to assure the initiation of a research program to fill data needs associated with the substances.

Section 104(i)(3) of CERCLA (42 U.S.C. 9604(i)(3)) outlines the content of

these profiles. Each profile will include an examination, summary and interpretation of available toxicological information and epidemiologic evaluations. This information and these data are to be used to ascertain the levels of significant human exposure for the substance and the associated health effects. The profiles must also include a determination of whether adequate information on the health effects of each substance is available or in the process of development. When adequate information is not available, ATSDR, in cooperation with the National Toxicology Program (NTP), is required to assure the initiation of research to determine these health effects.

Although key studies for each of the substances were considered during the profile development process, this **Federal Register** notice seeks to solicit any additional studies, particularly unpublished data and ongoing studies, which will be evaluated for possible addition to the profiles now or in the future.

The following draft toxicological profiles will be made available to the public on or about October 17, 1997.

| Document | Hazardous substance | CAS No. |
|---|---|---|
| 1. ..... | ALUMINUM ..... | 007429–90–5 |
| | ALUMINUM CHLORIDE. | 007446–70–0 |
| | ALUMINUM CHLOROHYDRATE. | 001327–41–9 |
| | ..... | 11097–68–0 |
| | ..... | 4861–98–3 |
| | ALUMINUM LACTATE. | 18917–91–4 |
| | ALUMINUM HYDROXIDE. | 021645–51–2 |
| | ALUMINUM OXIDE. | 001344–28–1 |
| | ALUMINUM NITRATE. | 13473–90–0 |
| | ALUMINUM PHOSPHATE. | 007784–30–7 |
| | ALUMINUM PHOSPHIDE. | 020859–73–8 |
| | ALUMINUM FLUORIDE. | 007784–18–1 |
| | ALUMINUM SULFATE. | 010043–01–3 |
| 2. ..... | CHLOROETHANE | 000075–00–3 |
| 3. ..... | CHLOROMETHANE. | 000074–87–3 |
| 4. ..... | 1,2-DICHLOROBENZENE. | 000095–50–1 |
| | 1,3-DICHLOROBENZENE. | 000541–73–1 |
| | 1,4-DICHLOROBENZENE. | 000106–46–7 |
| | CHLOROBENZENE. | 000108–90–7 |
| | DICHLOROBENZENE 025321–22–6. | |
| 5. ..... | 3,3,-DICHLOROBENZIDINE. | 00091–94–1 |
| 6. ..... | 2,4-DINITROTOLUENE. | 000121–14–2 |
| | 2,6-DINITROTOLUENE. | 000606–20–2 |
| 7. ..... | ETHYL BENZENE | 000100–41–4 |
| 8. ..... | HEXANE ..... | 000110–54–3 |
| 9. ..... | LEAD ..... | 007439–02–1 |
| 10. ..... | MERCURY ..... | 007439–97–6 |
| | MERCURIC (II) ACETATE. | 001600–27–7 |
| | MERCURIC (II) SULFIDE. | 001134–48–5 |
| | MERCURIC (I) CHLORIDE. | 010112–91–1 |
| | METHYLMERCURIC CHLORIDE. | 000115–09–3 |
| | PHENYLMERCURIC ACETATE. | 000062–38–4 |
| 11. ..... | PHENOL ..... | 000108–95–2 |
| 12. ..... | SULFURIC ACID .. | 007664–93–9 |
| | SULFUR TRIOXIDE. | 007446–11–9 |
| 13. ..... | SULFUR DIOXIDE | 007446–09–5 |

In regards to the draft Toxicological Profile for Mercury, it should be noted that the EPA is currently in the process of developing a comprehensive assessment of the potential adverse effects of mercury emissions on human health and wildlife. In addition, ATSDR is also aware of a number of other ongoing studies which are investigating the potential for human health effects from mercury exposure. Because of these special circumstances, ATSDR will monitor these efforts very closely during the public comment period; any meaningful and compelling information from these efforts will be critically evaluated for incorporation into the final Toxicological Profile for Mercury, as appropriate.

All profiles issued as ''Drafts for Public Comment'' represent ATSDR's best efforts to provide important toxicological information on priority hazardous substances. We are seeking public comments and additional information which may be used to supplement these profiles. ATSDR remains committed to providing a public comment period for these documents as a means to best serve public health and our clients.

Dated: October 22, 1997.

**Georgi Jones,**

*Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.*

[FR Doc. 97–28474 Filed 10–27–97; 8:45 am]

BILLING CODE 4163–70–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

**[ATSDR–129]**

### Availability of Draft Toxicological Profiles

**AGENCY:** Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

**ACTION:** Notice of availability.

**SUMMARY:** This notice announces the availability of two new draft toxicological profiles, comprising the 1st set developed for the Department of Energy, prepared by ATSDR for review and comment.

**DATES:** To ensure consideration, comments on these draft toxicological profiles must be received on or before February 17, 1998. Comments received after the close of the public comment period will be considered at the discretion of ATSDR based upon what is deemed to be in the best interest of the general public.

**ADDRESSES:** Requests for copies of the draft toxicological profiles or comments regarding the draft toxicological profiles should be sent to the attention of Ms. Loretta Norman, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

Requests for the draft toxicological profiles must be in writing, and must specifically identify the hazardous substance(s) profile(s) that you wish to receive. ATSDR reserves the right to provide only one copy of each profile requested, free of charge. In case of extended distribution delays, requestors will be notified.

Written comments and other data submitted in response to this notice and the draft toxicological profiles should bear the docket control number ATSDR–129. Send one copy of all comments and three copies of all supporting documents to the Division of Toxicology at the above address by the end of the comment period. Because all public comments regarding ATSDR toxicological profiles are available for public inspection after the profile is published in final, no confidential business information should be submitted in response to this notice.

**FOR FURTHER INFORMATION CONTACT:** Ms. Loretta Norman, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600

Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639–6322.

**SUPPLEMENTARY INFORMATION:** These toxicological profiles were developed by ATSDR for hazardous substances at Department of Energy (DOE) waste sites under Section 104(i) (3) and (5) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund). This public law directed ATSDR to prepare toxicological profiles for hazardous substances most commonly found at facilities on the CERCLA National Priorities List (NPL) and that pose the most significant potential threat to human health, as determined by ATSDR and the EPA. The current ATSDR priority list of hazardous substances at DOE NPL sites was announced in the **Federal Register** on July 24, 1996 (61 FR 38451).

Although key studies for each of the substances were considered during the profile development process, this **Federal Register** notice seeks to solicit any additional studies, particularly unpublished data and ongoing studies, which will be evaluated for possible addition to the profiles now or in the future.

The following draft toxicological profiles will be made available to the public on or about October 17, 1997.

| Document | Hazardous substance | CAS No. |
|---|---|---|
| 1. ..... | URANIUM ..... | Multiple |
| | URANIUM 235 ..... | 15117–96–1 |
| | URANIUM HEXAFLUORIDE. | 7783–81–5 |
| | URANIUM METAL | 7440–61–1 |
| | URANIUM ORE .... | 53125–22–7 |
| | URANIUM OCTAOXIDE. | 1344–59–8 |
| | URANIUM PEROXIDE. | 19525–15–6 |
| | URANIUM TETRACHLORIDE. | 10026–10–5 |
| | URANIUM TETRAFLUORIDE. | 10049–14–6 |
| | URANYL ACETATE. | 541–09–3 |
| | URANYL NITRATE | 10102–06–4 |
| | URANYL NITRATE HEXAHYDRATE. | 13520–83–7 |
| | URANYL SULFATE. | 1314–64–3 |
| 2. ..... | IONIZING RADIATION. | NA |

All profiles issued as ''Drafts for Public Comment'' represent ATSDR's best efforts to provide important toxicological information on priority hazardous substances. We are seeking public comments and additional information which may be used to supplement these profiles. ATSDR remains committed to providing a public comment period for these documents as a means to best serve public health and our clients.

Dated: October 22, 1997.

**Georgi Jones,**

*Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.*

[FR Doc. 97–28475 Filed 10–27–97; 8:45 am]

BILLING CODE 4163–70–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

**[ATSDR–127]**

### Availability of Draft Toxicological Profiles

**AGENCY:** Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

**ACTION:** Notice of availability.

**SUMMARY:** The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA) (42 U.S.C. 9604(i)(3)) directs the Administrator of ATSDR to prepare toxicological profiles of priority hazardous substances and to revise and publish each updated toxicological profile as necessary. This notice announces the availability of five updated drafts and three new draft toxicological profiles, comprising the 10th set of profiles, prepared by ATSDR for review and comment.

**DATES:** To ensure consideration, comments on these draft toxicological profiles must be received on or before February 17, 1998. Comments received after the close of the public comment period will be considered at the discretion of ATSDR based upon what is deemed to be in the best interest of the general public.

**ADDRESSES:** Requests for copies of the draft toxicological profiles or comments regarding the draft toxicological profiles should be sent to the attention of Ms. Loretta Norman, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

Requests for the draft toxicological profiles must be in writing, and must specifically identify the hazardous substance(s) profile(s) that you wish to receive. ATSDR reserves the right to provide only one copy of each profile requested, free of charge. In case of extended distribution delays, requestors will be notified.

Written comments and other data submitted in response to this notice and the draft toxicological profiles should bear the docket control number ATSDR–127. Send one copy of all comments and three copies of all supporting documents to the Division of Toxicology at the above address by the end of the comment period. Because all public comments regarding ATSDR toxicological profiles are available for public inspection after the profile is published in final, no confidential business information should be submitted in response to this notice.

**FOR FURTHER INFORMATION CONTACT:** Ms. Loretta Norman, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639–6322.

**SUPPLEMENTARY INFORMATION:** The Superfund Amendments and Reauthorization Act (SARA) (Pub. L. 99–499) amends the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) (42 U.S.C. 9601 *et seq.*) by establishing certain responsibilities for the ATSDR and the Environmental Protection Agency (EPA) with regard to hazardous substances which are most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these statutory provisions is that the Administrator of ATSDR prepare toxicological profiles for substances included on the priority lists of hazardous substances. These lists identified 275 hazardous substances that ATSDR and EPA determined pose the most significant potential threat to human health. The availability of the revised priority list of 275 hazardous substances was announced in the **Federal Register** on April 29, 1996 (61 FR 18744 ). For prior versions of the list of substances see **Federal Register** notices dated April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); and February 28, 1994 (59 FR 9486). CERCLA also requires ATSDR to assure the initiation of a research program to fill data needs associated with the substances.

Section 104(i)(3) of CERCLA (42 U.S.C. 9604(i)(3)) outlines the content of these profiles. Each profile will include an examination, summary and

interpretation of available toxicological information and epidemiologic evaluations. This information and these data are to be used to ascertain the levels of significant human exposure for the substance and the associated health effects. The profiles must also include a determination of whether adequate information on the health effects of each substance is available or in the process of development. When adequate information is not available, ATSDR, in cooperation with the National Toxicology Program (NTP), is required to assure the initiation of research to determine these health effects.

Although key studies for each of the substances were considered during the profile development process, this **Federal Register** notice seeks to solicit any additional studies, particularly unpublished data and ongoing studies, which will be evaluated for possible addition to the profiles now or in the future.

The following draft toxicological profiles will be made available to the public on or about October 17, 1997.

| Document | Hazardous substance | CAS No. |
|---|---|---|
| 1. ..... | CADMIUM ..... | 007440–43–9 |
| | CADMIUM CARBONATE. | 000513–78–0 |
| | CADMIUM CHLORIDE. | 010108–64–2 |
| | CADMIUM OXIDE | 01306–19–0 |
| | CADMIUM SULFATE. | 010124–36–4 |
| | CADMIUM SULFIDE. | 01306–23–6 |
| 2. ..... | CHLORODIBENZO-P-DIOXIN. | 039227–53–7 |
| | DICHLORODIBENZO-P-DIOXIN. | 050585–39–2 |
| | HEPTACHLORODIBENZO-P-DIOXIN. | 037871–00–4 |
| | HEXACHLORODIBENZO-P-DIOXIN. | 034465–46–8 |
| | OCTACHLORODIBENZO-P-DIOXIN. | 003268–87–9 |
| | PENTACHLORODIBENZO-P-DIOXIN. | 036088–22–9 |
| | TRICHLORODIBENZO-P-DIOXIN. | 039227–58–2 |
| | TETRACHLORODIBENZO-P-DIOXIN. | 041903–57–5 |
| | 1,2,3,4,6,7,8-HEPTACHLORODIBENZO-P-DIOXIN. | 035822–46–9 |
| 3. ..... | CHLOROPHENOLS. | 000088–06–2 |
| | 2,3,5,6-TETRACHLOROPHENOL. | 000935–95–5 |
| | 2,4,5-TRICHLOROPHENOL. | 000095–95–4 |
| | 2,4,6-TRICHLOROPHENOL. | 000088–06–2 |
| | 2-CHLOROPHENOL. | 000120–83–2 |
| | 4-Chlorophenol ..... | 000095–57–8 |
| | 2,3,4,5-TETRACHLOROPHENOL. | 004901–51–3 |
| | 2,3,4,6-TETRACHLOROPHENOL. | 000058–90–2 |
| 4. ..... | DORMALDEHYDE | 000050–00–0 |
| 5. ..... | HEXACHLOROCYCLOHEXANE. | 000608–73–1 |
| | HEXACHLOROCYCLOHEXANE, ALPHA-. | 000319–84–6 |
| | HEXACHLOROCYCLOHEXANE, BETA-. | 000319–85–7 |
| | HEXACHLOROCYCLOHEXANE, DELTA-. | 000319–86–8 |
| | HEXACHLOROCYCLOHEXANE, GAMMA-. | 000058–89–9 |
| 6. ..... | HEXACHLOROCYCLOPENTADIENE. | 000077–47–4 |
| 7. ..... | MANGANESE ..... | 007439–96–5 |
| 8. ..... | HYDROGEN SULFIDE. | 007783–06–4 |

All profiles issued as ''Drafts for Public Comment'' represent ATSDR's best efforts to provide important toxicological information on priority hazardous substances. We are seeking public comments and additional information which may be used to supplement these profiles. ATSDR remains committed to providing a public comment period for these documents as a means to best serve public health and our clients.

Dated: October 22, 1997.

**Georgi Jones,**

*Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.*

[FR Doc. 97–28476 Filed 10–27–97; 8:45 am]

BILLING CODE 4163–70–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Disease Control and Prevention

## Board of Scientific Counselors, National Center for Infectious Diseases: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

*Name:* Board of Scientific Counselors, National Center for Infectious Diseases (NCID).

*Times and Dates:* 11 a.m.–5:15 p.m., December 4, 1997; 8:30 a.m.–2:30 p.m., December 5, 1997.

*Place:* CDC, Auditorium B, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

*Status:* Open to the public, limited only by the space available.

*Purpose:* The Board of Scientific Counselors, NCID, provides advice and guidance to the Director, CDC, and Director, Page 2 NCID, in the following areas: program goals and objectives; strategies; program organization and resources for infectious disease prevention and control; and program priorities.

*Matters to be Discussed:* Agenda items will include:

1. NCID Update
2. Overview of CDC Emerging Infections Plan, 1998–2003
3. Charge to the Workgroups
4. Workgroup Sessions:

CDC Plan:

a. Surveillance and Response
b. Applied Research
c. Prevention and Control
d. Infrastructure Bioterrorism Preparedness

5. Workgroup Reports
6. Facilities Update
7. Scientific Updates (Late breakers)
8. Recommendations

Other agenda items include announcements/introductions; follow-up on actions recommended by the Board in May 1997; Page 3 and consideration of future directions, goals, and recommendations.

Agenda items are subject to change as priorities dictate.

Written comments are welcome and should be received by the contact person listed below prior to the opening of the meeting.

*Contact Person for More Information:* Diane S. Holley, Office of the Director, NCID, CDC, Mailstop C–20, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639-0078.

Dated: October 22, 1997.

**Julia M. Fuller,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 97–28480 Filed 10–27–97; 8:45 am]

BILLING CODE 4163–18–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Savannah River Site Health Effects Subcommittee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC), announce the following meeting.

*Name:* Citizens Advisory Committee on Public Health Service Activities and Research at DOE Sites: Savannah River Site Health Effects Subcommittee (SRS).

*Times and Dates:* 8 a.m.–4:15 p.m., November 13, 1997.

8 a.m.–11:45 a.m., November 14, 1997.

*Place:* Holiday Inn Midtown, 7100 Abercorn Street, Savannah, Georgia 31406, telephone 912/352–7100.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

*Background:* Under a Memorandum of Understanding (MOU) signed in December 1990 with DOE and replaced by an MOU signed in 1996, the Department of Health and Human Services (HHS) was given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS has delegated program responsibility to CDC.

In addition, an MOU was signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund''). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

*Purpose:* This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, regarding community, American Indian Tribes, and labor concerns pertaining to CDC's and ATSDR's public health activities and research at this DOE site. Activities shall focus on providing a forum for community, American Indian Tribal, and labor interaction and serve as a vehicle for community concern to be expressed as advice and recommendations to CDC and ATSDR.

*Matters to be Discussed:* Agenda items include: presentations from the National Center for Environmental Health (NCEH) regarding current activities and the National Institute for Occupational Safety and Health and ATSDR will provide updates on the progress of current studies.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Paul G. Renard, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Dated: October 22, 1997.

**Julia M. Fuller,**

*Acting Director, Management Analysis and Services Office Centers for Disease Control and Prevention (CDC).*

[FR Doc. 97–28484 Filed 10–27–97; 8:45 am]

BILLING CODE 4163–18–P

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[Document Identifier: HCFA–P–15A]**

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Current Beneficiary Survey (MCBS) Rounds: 20–28; *Form No.:* HCFA–P–15A (OMB# 0938–0568); *Use:* The MCBS is a continuous, multipurpose survey of a nationally representative sample of aged and disabled persons enrolled in Medicare. The survey provides a comprehensive source of information on beneficiary characteristics, needs, utilization, and satisfaction with Medicare-related activities; *Frequency:* Other (3 times a year per respondent); *Affected Public:* Individuals and households; *Number of Respondents:* 16,500; *Total Annual Responses:* 49,500; *Total Annual Hours:* 50,490.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: October 15, 1997.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.*

[FR Doc. 97–28436 Filed 10–27–97; 8:45 am]

BILLING CODE 4120–03–P

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## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–4263–N–46]**

### Environmental Review Procedures for Entities Assuming HUD Environmental Responsibilities; Notice of Proposed Information Collection for Public Comment

**AGENCY:** Office of the Assistant Secretary, Community Planning and Development (HUD).

**ACTION:** Notice of Proposed Information Collection for Public Comment.

**SUMMARY:** The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**DATES:** Comment due date: December 29, 1997.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Reports Liaison Officer, Sheila E. Jones, Department of Housing & Urban Development, 451 7th Street, SW, Room 7230, Washington, DC 20410–7000.

**FOR FURTHER INFORMATION CONTACT:** Richard H. Broun, Director, Office of Community Viability, Department of Housing and Urban Development, Room 7240, 451 Seventh Street, SW, Washington, DC 20410–7000. For telephone communication, contact Fred Regetz, Environmental Review Division at (202) 708–1201, Extension 4465. This is not a toll-free number. Hearing or speech impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

**SUPPLEMENTARY INFORMATION:** The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information 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; (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 collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

*Title of Proposal:* Environmental Review Procedures for Entities Assuming HUD Environmental Responsibilities.

*OMB Control Number:* 2506–0087.

*Description of the need for the information and proposed use:* To document compliance with the National Environmental Policy Act (NEPA) and the related environmental statutes. Used by recipients of HUD assistance who are required to assume HUD's environmental responsibilities. HUD regulations require recipients to submit requests for release of funds and certify full compliance with NEPA and the related statutes using the procedures identified in 24 CFR Part 58. Recipients must also maintain a public record of each project's compliance.

*Agency Form Numbers:* Form HUD 7015.15.

*Members of affected public:* State, Local or Tribal Government.

*Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:*

| Information collection | Number of responses | Responses per respondent | Total annual responses | Hours per response | Total hours | Regulatory reference |
|---|---|---|---|---|---|---|
| Office of Community Planning and Development | 2,500 | 1 | 2,500 | 0.6 | 1500 | § 58.1 |
| Office of Public and Indian Housing | 2,300 | 1 | 2,300 | 0.6 | 1380 | § 58.1 |
| Office of Housing | 125 | 1 | 125 | 0.6 | 75 | § 58.1 |
| Total Annual Burden | | | | 1.8 | 2875 | |

*Status of the proposed information collection:* The revision is needed in support of proposed rulemaking and request for OMB renewal for three years. The current OMB approval expires on December 31, 1998.

**Authority:** Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: October 22, 1997.

**Jacquie M. Lawing,**

*Acting Assistant Secretary for Community Planning and Development.*

BILLING CODE 4210–62–M

# Request for Release of Funds and Certification

**U.S. Department of Housing and Urban Development** OMB No. 2506-0087 (exp. 12/31/98)
Office of Community Planning and Development
Office of Public and Indian Housing
Office of Housing

Public reporting burden for this collection of information is estimated to average 0.6 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless that collection displays a valid OMB control number.
Pursuant to Section 104(g) of Title I, Housing and Community Development Act of 1974; Section 17(i) and Section 26 of the U.S. Housing Act of 1937; Title IV of the Stewart B. McKinney Homeless Assistance Act; Section 288 under Title II of the Cranston-Gonzales Nation Affordable Housing Act (NAHA); Section 542(c) and 1011(o) of the Housing and Community Development Act of 1992; Section 305(c) of the Multifamily Housing Property Disposition Reform Act of 1994; and Section 26 under title I of the United States Housing Act of 1937 for Public and Indian Housing.

| | |
|---|---|
| 1. Program Title(s): | 2. HUD/State Identification Number: |
| OMB Catalog No(s): | 3. Name & Address of Responsible Entity: |
| 4. Name & Address of Recipient: (if different from responsible entity) | 5. For information about this request, Contact: |
| | 6. Date of Latest Assistance Action: Application Submission: / Preliminary Approval: / Grant Agreement: |

DRAFT

**Part I. Request for Release of Funds** (to be completed by recipient)

7. HUD or State Agency & Office Unit to Receive Request:

The recipient(s) of assistance under the program listed above requests the release of funds and removal of grant conditions governing the use of the assistance for the following:

| | |
|---|---|
| 8. Program Activity/Project Name: | 9. Location: (street, address, city, county, & state) |

10. Program Activity/Project Description:

The recipient agrees to comply with any special conditions as evidenced in the environmental review performed by the responsible entity for carrying out the project in accord with 24 CFR 58.71(b) and (c).

| Signature of the recipient: | Title: | Date: |
|---|---|---|
| X | | |

form **HUD-7015.15** (10/16/97

Part 2. **Environmental Certification** (to be completed by responsible entity)

With reference to the above Program Activity/Project, I, the undersigned officer of the responsible entity, certify that:

1. The responsible entity has assumed responsibility for and complied with or will take into account, the National Environmental polic Act of 1969, as amended; the environmental procedures, permit requirements and statutory obligations of the laws cited in 24 CFR 58. and 24 CFR 58.6; and the applicable State and Local laws.
2. After considering the type and degree of environmental effects identified by the environmental review completed for the proposed projec described in Part 1 of this request, I have found that the proposal ☐ did ☐ did not require the preparation and dissemination of a environmental impact statement.
3. The responsible entity has disseminated and/or published in the manner prescribed by 24 CFR 58.43 a notice to the public in accordanc with 24 CFR 58.70 and as evidenced by the attached copy (copies).
4. The dates for all statutory and regulatory time periods for review, comment or other action are in compliance with procedures an requirements of 24 CFR Part 58.

As the duly designated certifying official of the responsible entity, I also certify that:

5. I am authorized to and do consent to assume the status of federal official under the National Environmental Policy Act of 19659 an each provision of law designated in the 24 CFR Part 58.5 and 24 CFR Part 58.6 list of NEPA-related authorities insofar as the provision of these laws apply to the HUD responsibilities for environmental review, decisionmaking and actions that have been assumed by th responsible entity.

6. I am authorized to and do accept, on behalf of the recipient personally, the jurisdiction of the federal courts for the enforcement of al

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| 7. Signature & Address of Certifying Officer of the Responsible Entity: | | |
|---|---|---|
| Signature: | Title: | Date: |
| X | | |

**Warning:** HUD will prosecute false claims and statements. Conviction may result in criminal and/or civil penalties (18 USC 1001, 1010, 1012; 31 USC 3729, 3802).

[FR Doc. 97–28471 Filed 10–27–97; 8:45 am]
BILLING CODE 4210–62–C

## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

## Public Scoping Meetings for Proposed Habitat Conservation Plan

**AGENCIES:** Fish and Wildlife Service, Interior; National Marine Fisheries Service, NOAA, Commerce.

**ACTION:** Notice of public scoping meetings.

**SUMMARY:** The Oregon Department of Forestry (Applicant) has begun the development of a Habitat Conservation Plan (Plan) for state forest lands managed by the Applicant. The Applicant intends to submit the Plan to the Fish and Wildlife Service and National Marine Fisheries Service (collectively, ''the Services''), along with an application for an incidental take permit under section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (Act).

This notice advises the public that the Services and Applicant have scheduled a series of public meetings to inform the public of a proposed Plan and the process of application for incidental take permits. The Services are seeking suggestions and information from other agencies and the public on the scope of issues related to the development of a Plan, including the range of alternatives that should be considered in the environmental review documents required under the National Environmental Policy Act. Public input may be written or oral (if provided at any of the public meetings). Information on dates and deadlines is provided below.

**DATES:** Comments should be received on or before February 3, 1998.

**ADDRESSES:** Comments regarding the scope of the environmental assessment or environmental impact statement should be labeled as ''Attention—ODF HCP'' and addressed to Mr. Russell Peterson at: Oregon State Office, Fish and Wildlife Service, 2600 SE 98th Avenue, Suite 100, Portland, Oregon 97266; telephone (503) 231–6179. Written comments may also be sent by facsimile to (503) 231–6195.

**FOR FURTHER INFORMATION:** Contact Mr. Joseph Zisa at the above address.

**SUPPLEMENTARY INFORMATION:**

### Background

The Applicant has initiated the development of a multi-species Habitat Conservation Plan under the provisions of section 10(a)(1)(B) of the Act, in consultation with the Services. The Plan will be submitted to the Services as part of an application for an incidental take permit for approximately 630,000 acres of state forest land. This acreage includes approximately 520,000 acres in the Tillamook and Clatsop State Forests in northwest Oregon and approximately 48,000 acres in the Santiam State Forest. The remaining covered acreage would include all other state forest lands west of the Cascade Mountains crest, with the exception of the Elliott State Forest in Coos and Douglas Counties. The Services issued an incidental take permit for the Elliott State Forest in 1995.

Once completed, the Applicant would submit the Plan as part of the incidental take permit application. The Services would evaluate the incidental take permit application and associated Plan in accordance with section 10(a)(2)(B) of the Act, and its implementing regulations. The environmental review of the Plan would be conducted in accordance with the requirements of the National Environmental Policy Act and its implementing regulations, as well as the implementing regulations of the Endangered Species Act. A No Action/No Project alternative will be considered consistent with the requirements of the National Environmental Policy Act.

The proposed incidental take permit would cover the Applicant's management activities that would result in the incidental take of species currently listed under the Act. Additionally, the applicant would be requesting federal assurances regarding other, presently unlisted species occurring or potentially occurring on the above lands. Presently listed species that the proposed Plan and incidental take permit would potentially cover include the threatened northern spotted owl (*Strix occidentalis caurina*), the threatened marbled murrelet (*Brachyramphus marmoratus marmoratus*), the threatened bald eagle (*Haliaeetus leucocephalus*), and the endangered American peregrine falcon (*Falco peregrinus anatum*). The proposed agreement covering conservation of unlisted species would include the proposed threatened coho salmon (*Oncorhynchus kisutch*) and other species.

During this scoping process, the Services seek public and agency input regarding the development of the proposed Plan and potential issuance of incidental take permits.

Should the decision be made that an environmental impact statement is appropriate, a separate Notice of Intent will be published in the **Federal Register**. Comments received during the scoping process referenced in this notice and any additional comments received following a future Notice of Intent shall be considered in the preparation of a draft environmental impact statement. At this time, the Services cannot estimate the time following the completion of this scoping process necessary for a decision regarding the selection of National Environmental Policy Act documentation and additional scoping.

Draft Plan and National Environmental Policy Act documents are not expected to be available for public review during this scoping process. The information gathered from scoping will be utilized in the development of such documents prior to a formal public review process later in 1998.

The Applicant is expected to present some of its proposals for the Plan to the public during the upcoming scoping meetings. These proposals do not necessarily represent those that will be included in the Plan as it undergoes further development. Such proposals may not be the product of complete consultation with the Services and have not been subject to formal evaluation for adequacy by the Services.

### Meetings

As an opportunity for interested persons to comment on the scope of the environmental assessment or environmental impact statement and issues related to the development of the Plan, public scoping meetings are scheduled as follows:

*November 17, 1997,* Oregon Department of Forestry District Office, 4907 Third Street, Tillamook, Oregon, 7:00 p.m. to 10:00 p.m.

*November 18, 1997,* Red Lion Inn, Chinook Room, 400 Industry Street, Astoria, Oregon, 7:00 p.m. to 10:00 p.m.

*November 20, 1997,* World Forestry Center, Portland, Oregon, 6:30 p.m. to 10:00 p.m., preceded by an informational workshop from 1:00 p.m. to 5:00 p.m.

*December 2, 1997,* Oregon Department of Forestry Headquarters, Conference Room, 2600 State Street, Salem, Oregon, 7:00 p.m. to 10:00 p.m.

*December 3, 1997,* Lane Community College, Forum Room 308, Eugene, Oregon, 7:00 p.m. to 10:00 p.m.

(For more detailed information regarding the above locations, please contact the Oregon Department of Forestry's Public Affairs Office at telephone (503) 945–7422 or (800) 482–6866.)

**Comments**

Comments received will be available for public inspection by appointment during normal business hours (8:00 a.m. to 5:00 p.m., Monday through Friday) at the above office. All comments received, including names and addresses, will become part of the administrative record and may be made available to the public.

**Authority:** This notice is being furnished pursuant to the Council on Environmental Quality Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act Regulations (40 CFR sections 1501.7 and 1508.22) to obtain suggestions and information from other agencies and the public on the scope of issues and alternatives that would be analyzed or considered in preparation of an environmental assessment or environmental impact statement.

Dated: October 22, 1997.

**Thomas J. Dwyer,**

*Acting Regional Director, Region 1, Portland, Oregon, Fish and Wildlife Service.*

[FR Doc. 97–28482 Filed 10–27–97; 8:45 am]

BILLING CODE 4310–55–P

## DEPARTMENT OF THE INTERIOR

## Bureau of Indian Affairs

### Notice of Intent to Prepare an Environmental Impact Statement for the Cabazon Band of Mission Indians Resource Recovery Park Project, Riverside County, California

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice of intent and public scoping meeting.

**SUMMARY:** This notice advises the public that the Bureau of Indian Affairs (BIA), with the cooperation of the Cabazon Band of Mission Indians, intends to gather information necessary for preparing a Programmatic Environmental Impact Statement (PEIS) for the Cabazon Resource Recovery Park Project proposed for development on Section 6 of the Cabazon Reservation in Riverside County, California. A description of the proposed project, location, and environmental considerations to be addressed in the PEIS are provided below (see supplemental information). In addition to this notice, a public meeting regarding the proposed project and preparation of the PEIS will be held.

This notice is published in accordance with the National Environmental Policy Act (NEPA) regulations found in 40 CFR 1501.7. The purpose of this notice is to obtain suggestions and information from other agencies and the public on the scope of issues to be addressed in the PEIS. Comments and participation in this scoping process are encouraged.

**DATES:** Comments must be received on or before November 28, 1997. A public scoping meeting will be held November 13, 1997, from 7 p.m. to 10 p.m.

**ADDRESSES:** Comments should be addressed to Ronald Jaeger, Area Director, Sacramento Area Office, Bureau of Indian Affairs, 4330 Watt Avenue, 4th Floor, North Higlands, California 95660. A public scoping meeting will be held on November 13, 1997, at the Tribal Hall, Cabazon Reservation, 84–245 Indio Springs Drive, Indio, California, from 7 p.m. to 10 p.m.

**FOR FURTHER INFORMATION CONTACT:** Frank Fryman, Acting Area Natural Resources Officer, Sacramento Area Office, Bureau of Indian Affairs, 4330 Watt Avenue, 4th Floor, North Higlands, California 95660, telephone number (916) 979–2575, extension 255; or Michael Derry, Development Manager, Cabazon Band of Mission Indians, 84–245 Indio Springs Drive, Indio, California 92201, telephone number (760) 342–2593, extension 3015.

**SUPPLEMENTARY INFORMATION:** The Cabazon Band of Mission Indians plans to develop Section 6 of their Reservation, located between Avenue 62 and Avenue 66 on State Highway 111, south of the City of Coachella in Riverside County, California, into the Cabazon Resource Recovery Park (CRRP). The CRRP will be developed to include numerous industrial facilities in the areas of recycling, reclamation, and reuse of materials that would otherwise be disposed of as waste, and subsequent manufacturing of products from the reclaimed materials. The CRRP will build on the existing waste recycling industries already constructed on Section 6. Future types of industries to be pursued include: a catalytic converter recycling plant in which platinum metal is recovered; a waste tire recycling plant which will produce crumb rubber for numerous industrial and paving uses; a materials recovery facility (MRF) which will separate reusable materials from the municipal solid waste stream; a biomass to ethanol facility; a building block production facility; and a specialty plastic products manufacturer using plastics recovered at the MRF. Numerous other projects similar in nature are planned. An infrastructure will be constructed to support the facilities in the Park, including rail sidings, a road network, a sewage treatment plant, and a cogeneration plant. The project will use the existing Southern Pacific rail line and the improved State Highway 86 for transportation of materials to and from the Park. The PEIS will address existing, developing, planned, and representative projects in the CRRP. Areas of environmental concern include: air quality, traffic and transportation, biological and botanical resources, and cultural resources. The range of issues addressed may be expanded based on comments received during the scoping process.

**Ada E. Deer,**

*Assistant Secretary—Indian Affairs.*

[FR Doc. 97–28492 Filed 10–27–97; 8:45 am]

BILLING CODE 4310–02–P

## DEPARTMENT OF THE INTERIOR

## Bureau of Land Management

**[WO–310–1310–01–24–1A; OMB Approval Number 1004–0136]**

### Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The Bureau of Land Management (BLM) has submitted the proposed collection for information listed below to the Office of Management and Budget (OMB) for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 3501 *et seq.*). On April 8, 1996, the BLM published a notice in the **Federal Register** (61 FR 15510) requesting comments on the collection. The comment period ended June 7, 1996. No comments were received. Copies of the proposed collection of information and related forms and explanatory material may be obtained by contacting the BLM Clearance Officer at the telephone number listed below.

OMB is required to respond to this request within 60 days but may respond after 30 days. For maximum consideration your comments and suggestions on the requirements should be made within 30 days directly to the Office of Management and Budget, Interior Department Desk Officer (1004–0136), Office of Information and Regulatory Affairs, Washington, D.C., 20503, telephone (202) 395–7340. Please provide a copy of your comments to the Bureau Clearance Office (WO–630), 1849 C St., N.W., Mail Stop 401 LS, Washington, D.C. 20240.

*Nature of Comments:* We specifically request your comments on the following:

1. Whether the collection of information is necessary for the proper functioning of the Bureau of Land

Management, including whether the information will have practical utility;

2. The accuracy of BLM's estimate of the burden of collecting the information, including the validity of the methodology and assumptions used;

3. The quality, utility and clarity of the information to be collected; and

4. How to minimize the burden of collecting the information on those who are to respond, including the use of appropriate automated electronic, mechanical, or other forms of information technology.

*Title:* Application for Permit for Drill, Deepen, or Plug Back.

*OMB Approval Number:* 1004–0136.

*Abstract:* Data submitted by oil and gas operators is used for agency approval of proposed drilling operations through review of technical and environmental factors.

*Bureau Form Number:* 3160–3.

*Frequency:* On occasion.

*Description of Respondents:* Oil and gas operators.

*Estimated Completion Time:* 30 minutes.

*Annual Responses:* 4,000.

*Annual Burden Hours:* 2,000.

*Bureau Clearance Officer:* Carole Smith (202) 452–0367.

Dated: September 29, 1997.

**Carole Smith,**

*Bureau of Land Management Information Clearance Officer.*

[FR Doc. 97–28445 Filed 10–27–97; 8:45 am]

BILLING CODE 4310–84–M

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## DEPARTMENT OF THE INTERIOR

## Bureau of Land Management

**[AZ917–AZA29960]**

## Notice of Proposed Decision of Exchange of Lands in Maricopa and Pima Counties, Arizona

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that on October 17, 1997 Michael A. Taylor, Phoenix Field Office Manager, approved the proposed land exchange between the Bureau of Land Management, Phoenix Field Office and Tucson Mountain Investors, L.L.C. The proposed decision, the Finding of No Significant Impact (FONSI) and the Environmental Assessment (EA) are available for public review at the State Office, 222 North Central Avenue, Phoenix, Arizona 85004. Copies can also be obtained by calling Alicia A. Leone at (602) 417–9567. The following described federal land has been determined to be suitable for transfer out of federal ownership by exchange pursuant to Section 206 of the Federal Land Policy and Management Act of 1976 (U.S.C. 1716), as amended:

**Gila and Salt River Meridian, Arizona**

T. 5 N., R. 1 W.,
Sec. 1, lots 1–7, SW¼NE¼, S½NW¼, SW¼, W½SE¼;
Sec. 3, SW¼SW¼SW¼;
Sec. 4, SW¼SW¼, SW¼SE¼, W½SE¼SW¼SE¼, E½SW¼SE¼SE¼, SE¼SE¼SE¼;
Sec. 5, E½SE¼;
Sec. 7, N½NE¼, N½S½NE¼, NE¼NW¼;
Sec. 8, N½NE¼, E½W½E½SE¼SE¼, E½E½SE¼SE¼;
Sec. 9, all;
Sec. 10, all;
Sec. 11, all;
Sec. 14, lots 1–10, NW¼NE¼, N½NW¼, NE¼SW¼, S½SW¼;
Sec. 15, lots 1–10, N½NE¼, SW¼NE¼, NW¼, N½SW¼;
Sec. 22, N½N½, SW¼NW¼.

The area described contains 4,322.40 acres.

In exchange the United States will acquire the following described land from Tucson Mountain Investors, L.L.C.:

**Gila and Salt River Meridian, Arizona**

T. 13 S., R. 12 E.,
Sec. 10, part of;
Sec. 11, part of.

The area described contains 632.78 acres more or less.

Approval of the exchange is to implement the Phoenix Resource Management Plan Decision which identified the selected federal lands for disposal and on development information submitted by Noranda Properties, Inc. Acquisition of the private lands was authorized by Public Law 103–364, signed into law in October 1994, which added 3,460 acres to the park and changed the name from Saguaro National Monument to Saguaro National Park. Resource values of the private lands enhance the resource management within the Saquaro National Park. The offered lands contain representative Sonoran Desert vegetation in excellent condition. The diversity of vegetation, representing the paloverde/saguaro/mixed cactus and ironwood associations, provides important habitat for some of the sensitive wildlife species which occur in the Arizona Upland vegetation type. Also as part of the Saguaro National Park, the area will be accessible to hikers, horseback riders, birdwatchers, botanists and students of natural history. The public interest will be served by making the exchange.

**ADDRESSES:** Interested parties may submit comments and/or protests concerning the Proposed Decision for the exchange to the Bureau of Land Management, Phoenix Field Office 2015 West Deer Valley Road, Phoenix, Arizona 85027. Comments must be in writing to the Field Office Manager and be postmarked within 45 days from the publication of this notice.

Dated: October 17, 1997.

**Michael A. Taylor,**

*Field Manager.*

[FR Doc. 97–28512 Filed 10–27–97; 8:45 am]

BILLING CODE 4310–32–M

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## DEPARTMENT OF THE INTERIOR

## Bureau of Land Management

**[ES–960–1910–12] ES–48891, Group 29, Illinois**

## Notice of Cancellation of Plat of Survey

The plat accepted July 11, 1997 published in the **Federal Register** on July 22, 1997 (62 FR 39249) and stayed August 28, 1997 published August 28, 1997 (62 FR 45680) has been cancelled effective October 17, 1997.

Dated: October 20, 1997.

**Stephen G. Kopach,**

*Chief Cadastral Surveyor.*

[FR Doc. 97–28446 Filed 10–27–97; 8:45 am]

BILLING CODE 4310–GJ–M

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## DEPARTMENT OF THE INTERIOR

## National Park Service

## Final Environmental Impact Statement/General Management Plan; San Francisco Maritime National Historical Park, California; Record of Decision

### Introduction

Pursuant to § 102(2)(C) of the National Environmental Policy Act of 1969, Pub. L. 91–190 (as amended), and the regulations promulgated by the Council on Environmental Quality at 40 CFR 1505.2, the Department of the Interior, National Park Service, has prepared this Record of Decision (ROD) for the Final Environmental Impact Statement on the General Management Plan for San Francisco Maritime National Historical Park. The ROD is a concise statement of what decisions were made, what alternatives were considered, the environmentally preferred alternative, the basis for the decision, and the mitigating measures developed to avoid or minimize environmental impacts.

### Selected Action

The National Park Service (NPS) will implement Alternative A, described as the proposed action in the Draft and

Final Environmental Impact Statements (EIS). The NPS will emphasize the preservation and maintenance of the park's collection, including the fleet of historic vessels, small watercraft, historic structures, library, and archival materials. Minimal measures to slow down deterioration of the steam schooner Wapama will be implemented, but the vessel's underlying structural decay will not be addressed. The park will pursue multiple strategies for ship restoration, such as continued use of commercial shipyards and appropriate agreements with San Francisco Bay Area dry dock facilities. Efforts will be made to seek out other agencies or private organizations interested in reconstructing or preserving Wapama as a dryberth exhibit. If such efforts are unsuccessful, the ship will be dismantled when it can no longer be maintained in a safe condition. Wapama will suffer an adverse effect if she is dismantled. Greater use of the park's collection by the public for research and interpretive purposes will be provided through the use of additional facilities, including rehabilitation of the Haslett Warehouse. The intersection of Hyde and Jefferson Streets will be redesigned to enhance pedestrian access and visibility of the pier and historic ships, and to expand interpretive opportunities. Aquatic Park will be enhanced and maintained as a public open space, and recreational activities in the lagoon such as swimming, rowing, and the temporary mooring of sailboats will continue to be provided to all users. Park volunteer programs will be enhanced and visitors will be encouraged to experience other related sites in the San Francisco Bay Area. Historic properties will generally benefit from a consistent maintenance and preservation approach aimed at perpetuating their historic integrity. The library and museum collection will receive the space, equipment, and staffing needed to protect, preserve, and use them appropriately. Local traffic patterns and parking will be affected during peak use times. There will be minor disturbance along the shoreline from construction activities.

**Other Alternatives Considered**

Two alternatives to the selected plan were detailed and evaluated in the Draft and Final EIS documents. Alternative B emphasized preservation and maintenance of the historic ships, small watercraft, historic structures, library, and archival materials. Space would be upgraded and expanded for the park's collection. The park would pursue multiple strategies for major ship restoration work. The intersection of Hyde and Jefferson Streets would be further developed as an expanded-permanent pedestrian plaza with public seating, unobstructed views of the ships and Bay, and additional space for interpretive demonstrations, displays, and public programs. Impacts from Alternative B would be very similar to the selected action, except: the Eppleton Hall would be deaccessioned; there would be a permanent change in local traffic and parking patterns; the swimming and rowing clubs would be relocated to the west side of the Aquatic Park lagoon; and slightly more disturbance from construction activities along the shoreline would occur.

Alternative C (No Action-Minimum Requirements) would continue current management strategies, with minimum actions implemented to stabilize and preserve the park's collection and historic properties.

**Environmentally Preferred Alternative**

The NPS has determined Alternative A (the selected action) to be the environmentally preferred alternative. It causes the least damage to the biological environment; it best protects, preserves, and enhances historic, cultural, and natural resources; and it would disturb the least acreage. Both Alternative A and Alternative B would greatly benefit the preservation and maintenance of the park's collection. Both alternatives would improve the visitor experience through creation of a pedestrian plaza, although under Alternative B the plaza would be expanded and permanent. Creation of a pedestrian plaza would result in some adverse effects on traffic and parking, which would primarily be confined to certain times during summer weekends under Alternative A.

**Basis for Decision**

As presented in the Draft EIS, the National Park Service developed twenty-six (26) management objectives, covering resource management, visitor experience, park development/facility design, and local context. After evaluation of public comments on the alternatives presented in the Draft EIS, it was determined that the selected action best achieves the stated management objectives and achieves the park's purpose which is to preserve and interpret the history and achievements of seafaring Americans and the Nation's maritime heritage, especially on the Pacific Coast.

**Measures to Minimize Harm**

The NPS consulted with the California State Historic Preservation Officer and Advisory Council on Historic Preservation according to the Council's implementing regulations (36 CFR 800). A Programmatic Agreement completed April 25, 1997 stipulates mitigative measures that will be implemented. Further conservation planning and impact analysis will be conducted for any individual construction projects, and recorded in separate environmental decision documents subject to public review. Appropriate mitigation, such as erosion control measures, would be identified during that time. A traffic and transportation analysis will be completed before implementing any vehicular access/circulation or parking proposals.

**Conclusion**

The above factors and considerations warrant selection of the alternative identified as the proposed action in the Final EIS.

Dated: October 9, 1997.

**Patricia L. Neubacher,**

*Acting Regional Director, Pacific West Region.*

[FR Doc. 97–28497 Filed 10–27–97; 8:45 am]

BILLING CODE 4310–70–P

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## DEPARTMENT OF THE INTERIOR

## National Park Service

## Environmental Impact Statement/ General Management Plan; Sequoia & Kings Canyon National Parks, California; Notice of Intent

**Summary**

Pursuant to the National Environmental Policy Act of 1969 (Public Law 91–190, as amended), and in accordance with the President's Council of Enviromental Quality regulations promulgated at 40 CFR 1501.7 and 1508.22, the National Park will prepare an Environmental Impact Statement (EIS) for a General Management Plan (GMP) intended to guide management activities for Sequoia and Kings Canyon National Parks during the next 10–15 years.

**Background**

The purpose of the GMP is to set forth the basic management philosophy for the parks and provide strategies for addressing issues and achieving identified management objectives. The EIS will identify and evaluate forseeable environmental impacts (and associated mitigation measures) of a range of alternatives formulated to address distinct management issues for the parks and strategies identified for resource protection, visitor uses, facility development, and adjacent federal, state, and lands. As a conceptual

framework for formulating these alternatives, the park's purposes and significance will first be identified. Based upon purpose, significance, and strategies identified, the GMP will identify and analyze programs, actions, and support facilities needed for implementation.

**Public Information**

Earlier in the scoping process a series of public forums was announced and conducted. Additional public open house/workshops are scheduled for fall 1997, which will be publicized through mailings, press releases, park information media, and public notices (details will be available upon request via the contact listed below). A record of all information obtained through these sessions will be maintained during the entire EIS process. Also, a series of newsletters will be distributed throughout.

**Comments**

All interested individuals, organizations, agencies, or entities that may be affected by the proposed plan are encouraged to share comments about issues or concerns which should be addressed during the EIS process. Written comments concerning the GMP/EIS should be postmarked no later than sixty (60) days from the publication date of this notice. All comments, or inquiries regarding public forums, should be addressed to: Planning Team Captain, National Park Service, Denver Service Center, 12795 West Alameda Parkway, Denver, Colorado 80225–0287 or via telephone at (303) 969–2280.

**Decision**

The draft EIS and plan are anticipated to be available for public review during summer, 1998. The final EIS and plan are expected to be completed one year later. A complete Record of Decision is to be executed no sooner than thirty days after the release of the final EIS. The responsible officials are John Reynolds, Regional Director, Pacific West Regional Office, National Park Service; Michael Tollefson, Superintendent, Sequoia and Kings Canyon National Parks.

Dated: October 8, 1997.

**Patricia L. Neubacher,**

*Acting Regional Director, Pacific West Region.*

[FR Doc. 97–28498 Filed 10–27–97; 8:45 am]

BILLING CODE 4310–70–P

## DEPARTMENT OF THE INTERIOR

## National Park Service

## Subsistence Resource Commission; Notice of a Meeting

**ACTION:** Subsistence Resource Commission (SRC) meeting.

**SUMMARY:** The Superintendent of Aniakchak National Monument and the Chairperson of the Subsistence Resource Commission for Aniakchak National Monument announce a forthcoming meeting of the Aniakchak National Monument Subsistence Resource Commission.

The following agenda items will be discussed:

(1) Call to order. (Chairman)
(2) SRC Roll call; confirmation of quorum. (Chairman)
(3) Welcome and introductions (Public, agency staff, others).
(4) Review and adopt agenda. (SRC)
(5) Review and adopt minutes from the February 1997 meeting.
(6) Review commission's role and purpose.
(7) Status of commission membership.
(8) Old business:
  a. Recommendation to designate Ivanof Bay and Perryville as resident zone communities.
  b. Status of Board of Game and Federal Subsistence Board proposals to close Unit 9E to non-subsistence/sport taking of moose and caribou.
  c. NPS Unit 9E moose and caribou population surveys.
  d. Aniakchak National Monument and Preserve visitor use report for 1997.
  e. Status of Aniakchak National Preserve Hunting Guide prospectus.
  f. Status of NPS subsistence program document/SRC chair briefing session.
  g. Review and approve final subsistence hunting program recommendations.
(9) New business:
  a. Federal Subsistence Program update.
  b. Public and agency comments.
(10) SRC work session (draft proposals, letters, hunting program recommendations).
(11) Set time and place of next SRC meeting.
(12) Adjournment.

**DATES:** The meeting will begin at 1:00 p.m. on Thursday, November 13, 1997 and conclude at approximately 7:00 p.m. The meeting will reconvene at 8:00 a.m. on Friday, November 14, 1997 and adjourn at approximately 1:00 p.m.

**LOCATION:** The meeting will be held at the Chignik Lake School in Chignik Lake, Alaska.

**FOR FURTHER INFORMATION CONTACT:** Bill Pierce, Superintendent, or Karen C. Gustin, Unit Manager, Aniakchak National Monument, P.O. Box 7, King Salmon, Alaska 99613. Phone (907) 246–3305.

**SUPPLEMENTARY INFORMATION:** The Subsistence Resource Commissions are authorized under Title VIII, Section 808, of the Alaska National Interest Lands Conservation Act, Pub. L. 96–487, and operate in accordance with the provisions of the Federal Advisory Committees Act.

**Marcia Blaszak,**

*Acting Regional Director, Alaska Region.*

[FR Doc. 97–28500 Filed 10–27–97; 8:45 am]

BILLING CODE 4310–70–P

## DEPARTMENT OF THE INTERIOR

## National Park Service

## Meeting of Federal Interagency Panel on World Heritage

**AGENCY:** National Park Service, U.S. Department of the Interior.

**ACTION:** Notice of meeting of panel.

**SUMMARY:** Notice is hereby given in accordance with the Federal Advisory Committees Act (Pub. L. 92–463, 86 Stat. 770, 5 U.S.C. App. I), of a meeting of the Federal Interagency Panel on World Heritage. It is expected that the following agenda items will be discussed:

Results of 21st Meeting of the World Heritage Bureau
Results of the General Assembly of States Parties to the World Heritage Convention
Agenda for and United States Representation at the 21st Meeting of the World Heritage Committee
Report on Legislative Proposals potentially affecting U.S. World Heritage Program
Public Information Activities, including new National Park Service World Heritage Leaflet
U.S. World Heritage Nomination Process for 1998

**DATES:** The meeting will be held on Monday, November 3, 1997. The meeting will begin at 2:00 pm and end by approximately 5 pm. The meeting is open to the public. It is expected that 10 persons will be able to attend the meeting in addition to the Panel members.

**LOCATION:** The meeting will be held at the Main Interior Building, 1849 C St., NW, Washington, DC., in Room 3121.

**FOR FURTHER INFORMATION CONTACT:** Sharon J. Cleary, Chief, Office of International Affairs, or James H. Charleton, International Cooperation Specialist, Office of International

Affairs, National Park Service, Washington, DC 20240. Phone (202) 565–1280; fax 202–565–1290; e-mail: james—charleton @ nps.gov.

**ADDRESSES:** Written comments or recommendations should be sent to the Director, National Park Service, U.S. Department of the Interior, P.O. Box 37127, Washington, D.C. 20240. Attention: World Heritage Convention-0050.

**SUPPLEMENTARY INFORMATION:** The Convention Concerning Protection of the World Cultural and Natural Heritage, now ratified by the United States and 149 other countries, has established a system of international cooperation through which cultural and natural properties of outstanding universal value to humanity may be recognized and protected.

The Convention seeks to put into place an orderly approach for coordinated and consistent heritage resource protection and enhancement throughout the world.

Participating nations voluntarily identify and nominate their most important natural wonders and cultural treasures for inclusion on the World Heritage List, which currently includes 506 cultural, natural, and mixed properties. The World Heritage Committee judges all nominations against established criteria.

Under the Convention, each participating Nation assumes responsibility for taking appropriate legal, scientific, technical, administrative, and financial measures necessary for the identification, protection, 2 conservation, and rehabilitation of World Heritage properties situated within its borders. By the terms of the Convention, each nation explicitly retains full sovereignty over and complete ownership, legal authority and management responsibility for its World Heritage Sites. In the United States, for example, only United States law applies to the sites.

The World Heritage Committee, composed of 21 countries elected by the signatories to the Convention, reviews proposals to add new sites to the List once each year. The United States now serves on the Committee and has twice served as its Chair. The Committee administers the World Heritage Fund, which assists countries in participating in World Heritage activities related to the preservation of listed properties, particularly those on a List of World Heritage in Danger maintained by the Committee.

The United States has placed 20 sites on the List. Among them are Monticello and the Taos Pueblo, nominated with their owners' full support. National Parks are included in 17 World Heritage Sites—among which are the Grand Canyon, Independence Hall, Mammoth Cave, and Everglades. Two sites in the United States are on the List of World Heritage in Danger—Everglades and Yellowstone National Parks.

No United States nominations to the World Heritage List are pending. The Panel will review the process for possible U.S. nominations in calendar 1998 that might lead to consideration of sites for inscription in the World Heritage List at the World Heritage Committee meeting scheduled for the end of calendar 1999.

In the United States, the Department of the Interior is responsible for directing and coordinating U.S. participation in the World Heritage Convention. The Department implements its responsibilities under the Convention in accordance with the statutory mandate contained in Title IV of the National Historic Preservation Act Amendments of 1980 (P.L. 96–515; 16 U.S.C. 470a–1, a–2). On May 27, 1982, the Interior Department published in the **Federal Register** the policies and procedures which it uses to carry out this legislative mandate (47 FR 23392, 36 CFR 73). The rules contain additional information on the Convention and its implementation in the United States, and identify the specific requirements that U.S. properties must satisfy before they can be nominated for World Heritage status, i.e., the property must have previously been determined to be of national significance, its owner must concur in writing to its nomination, and its nomination must include evidence of such legal protections as may be necessary to ensure preservation of the property and its environment.

The program regulations; the criteria which cultural, natural, and mixed properties must satisfy for World Heritage status; the properties on the Indicative Inventory of Potential Future U.S. World Heritage nominations; and a list of the 20 U.S. properties inscribed on the World Heritage List as of the date of this notice are available upon request from the National Park Service.

The Federal Interagency Panel for World Heritage assists the Department in implementing the Convention by making recommendations on U.S. World Heritage policy, procedures, and nominations. The Panel is chaired by the Assistant Secretary for Fish and Wildlife and Parks, and currently includes representatives from the Office of the Assistant Secretary for Fish and Wildlife and Parks, the National Park Service, the Bureau of Land Management, the U.S. Fish and Wildlife Service, and the U.S. Geological Survey within the Department of the Interior; the President's Council on Environmental Quality; the Smithsonian Institution; the Advisory Council on Historic Preservation; the National Oceanic and Atmospheric Administration, Department of Commerce; the U.S. Forest Service, Department of Agriculture; the U.S. Information Agency; and the Department of State.

Dated: October 7, 1997.

**Sharon J. Cleary,**

*Chief, Office of International Affairs.*

[FR Doc. 97–28499 Filed 10–27–97; 8:45 am]

BILLING CODE 4310–70–P

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## DEPARTMENT OF THE INTERIOR

## National Park Service

## National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before October 18, 1997. Pursuant to section 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, P.O. Box 37127, Washington, D.C. 20013–7127. Written comments should be submitted by November 12, 1997.

**Carol D. Shull,**

*Keeper of the National Register.*

### Colorado

Dolores County

Ansel Hall Ruin (Great Pueblo Period of the McElmo Drainage Unit MPS), Address Restricted, Cahone vicinity, 97001418

Mesa County

Phillips, Harry and Lilly, House, 798 N. Mesa St., Fruita, 97001419

### Florida

Polk County

Frostproof High School, Old, 111 W. First St., Frostproof, 97001420

### Georgia

Cherokee County

Canton Wholesale Company Building, 15 Main St., Canton, 97001421

**Indiana**

Vigo County

Indiana Theatre (Downtown Terre Haute MRA), 683 Ohio St., Terre Haute, 83004578

**Louisiana**

East Baton Rouge Parish

Drehr Place Historic District, Roughly bounded by Government, 22nd, Myrtle, and St. Rose Sts., Baton Rouge, 97001422

St. Tammany Parish

Griffin's Bakery, 301 Lafitte St., Mandeville, 97001423

**Minnesota**

Hennepin County

Prospect Park Water Tower and Toeer Hill Park, 55 Malcolm Ave. SE, Minneapolis, 97001426

Nobles County

Church of St. Kilian (Catholic), Approx. 3 mi. NW of Wilmont, Wilmont Township vicinity, 97001425

Rice County

Church of the Most Holy Trinity (Catholic), 4938 N. Washington St., Wheatland Township vicinity, 97001424

**Mississippi**

Marshall County

Wall Doxey State Park (State Parks of Mississippi built by the CCC MPS), Between MS 7 and Spring Lake, Holly Springs vicinity, 97001437

Scott County

Roosevelt State Park (State Parks in Mississippi built by the CCC MPS), 2149 MS 13S, Morton vicinity, 97001436

**Missouri**

Howard County

Campbell Chapel African Methodist Episcopal Church, 602 Commerce St., Glasgow, 97001427

Lafayette County

Buck, Napoleon, House (Antebellum Resources of Johnson, Lafayette, Pettis, and Saline Counties MPS), 0.40 mi. S of jct. of US 24 and MO 273, Waverly vicinity, 97001431

Catron, Minatree, House (Antebellum Resources of Johnson, Lafayette, Pettis, and Saline Counties MPS), 0.1 mi W of jct. of US 24 and MO 110, Lexington vicinity, 97001432

Dinwidile, James M., House (Antebellum Resources of Johnson, Lafayette, Pettis, and Saline Counties MPS), 0.25 mi. E of jct. of US 24 and MO 184, Dover vicinity, 97001430

Gosewisch, Theodore, House (Antebellum Resources of Johnson, Lafayette, Pettis, and Saline Counties MPS), 0.5 mi. W of jct. of MO 13 and Marshall School Rd., Lexington vicinity, 97001433

Robinson, William, P., House (Antebellum Resources of Johnson, Lafayette, Pettis, and Saline Counties MPS), 0.2 mi. E and 0.15 mi. S of jct. of MO 107 and MO 112, Lexington vicinity, 97001428

Shelby, Thomas, House (Antebellum Resources of Johnson, Lafayette, Pettis, and Saline Counties MPS), 0.25 mi. E of US 24 and MO 111, Lexington vicinity, 97001429

Pettis County

Gentry, William H., House (Antebellum Resources of Johnson, Lafayette, Pettis, and Saline Counties MPS), 22970 Cherry Tree Ln., Sedalia vicinity, 97001434

Saline County

Murrell, George A., House (Antebellum Resources of Johnson, Lafayette, Pettis, and Saline Counties MPS), 0.75 mi. E and 0.5 mi. N of MO E and H, Napton vicinity, 97001435

**New York**

Kings County

Cypress Hills National Cemetery (Civil War Era National Cemeteries MPS), 625 Jamaica Ave., Brooklyn, 97001439

**Tennessee**

Knox County

Keener, Leroy, House (Knoxville and Knox County MPS), 3506 Woodlawn School Rd., Knoxville vicinity, 97001440

Shelby County

Chickasaw Heritage Park, Jct. of Riverside Blvd. and Ornamental Metal Museum Dr., Memphis, 97001441

Williamson County

Dortch Stove Works, 230 N. Franklin Rd., Franklin, 97001438

**Vermont**

Franklin County

Kemp—Shepard House, VT 104A, 1 mi. SE of US 7, Georgia, 97001442

**Wisconsin**

Clark County

Foote, Charles, House, W 5055 US 10, Pine Valley, 97001443

Proposed Move

**Alaska**

Southeast Fairbanks County

Sullivan Roadhouse, Mi. 266, Richardson Hwy Delta Junction, 79003757.

[FR Doc. 97–28477 Filed 10–27–97; 8:45 am]

BILLING CODE 4310–70–P

## DEPARTMENT OF JUSTICE

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Office of Community Oriented Policies Services, Justice.

**ACTION:** Notice of Information Collection Under Emergency Review; Regional Community Policing Institute Quarterly Projection Report.

The Department of Justice, Office of Community Oriented Policing Services has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the emergency review procedures of the Paperwork Reduction Act of 1995; 5 Code of Federal Regulation, Part 1320.13.

The proposed information collection is published to obtain comments from the public and affected agencies. Emergency review and approval of this collection has been requested from OMB by October 31, 1997. If granted, the emergency approval is only valid for 180 days. All comments should be directed to OMB, Office of Information and Regulatory Affairs: Attention: Mr. Patrick Boyd, 202–395–5871, Department of Justice Desk Officer, Washington, DC 20503.

During the first 60 days of this same period, a regular review of this information collection is also being undertaken. Comments are encouraged and will be accepted until December 29, 1997. Comments should address one or more of the following four points:

(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.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC, 20530. Additionally, comments may be submitted to OMB via facsimile to 202–395–7285. Comments may also be submitted to the Department of Justice (DOJ), Justice Management Division, Information Management and Security Staff, Attention: Department Clearance Officer, Suite 850, 1001 G Street, NW, Washington, DC, 20530. Additionally, comments may be submitted to DOJ via facsimile to 202–514–1534. Written comments may also be submitted to Charlotte C. Grzebien, Associate General Counsel, Office of Community Oriented Policing Services, 1100 Vermont Avenue, N.W., Washington, D.C. 20530, or via facsimile at (202) 514–3456.

Overview of this information collection:

(1) *Type of Information collection:* New collection.

(2) *Title of the Form/Collection:* Regional Community Policing Institute Quarterly Projection Report.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form: COPS 22/02. Office of Community Oriented Policing Services, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Regional Community Policing Institutes funded through a one-year cooperative agreement from the COPS Office are required to respond.

The Regional Community Policing Institute Quarterly Projection Report will be completed by each Regional Community Policing Institute. The information collected provides a quarterly projection of plans for performing the training and technical assistance functions of this program, as well as information concerning any changes or modifications requested in the project or cooperative agreement budgets.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent of respond:* Estimated number respondents: 35. Estimated time for average respondent to respond: 2 hours quarterly (including record-keeping).

(6) *An estimate of the total public burden (in hours) associated with the collection:* Approximately 280 annual burden hours.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: October 23, 1997.

**Robert B. Briggs,**

*Department Clearance Officer, United States Department of Justice.*

[FR Doc. 97–28514 Filed 10–27–97; 8:45 am]

BILLING CODE 4410–01–M

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## DEPARTMENT OF JUSTICE

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Office of Community Oriented Policing Services, Justice.

**ACTION:** Notice of information collection under emergency review; Regional Community Policing Institute monthly progress report.

The Department of Justice, Office of Community Oriented Policing Services has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the emergency review procedures of the Paperwork Reduction Act of 1995; 5 Code of Federal Regulation, Part 1320.13.

The proposed information collection is published to obtain comments from the public and affected agencies. Emergency review and approval of this collection has been requested from OMB by October 31, 1997. If granted, the emergency approval is only valid for 180 days. All comments should be directed to OMB, Office of Information and Regulatory Affairs: Attention: Mr. Patrick Boyd, 202–395–5871, Department of Justice Desk Officer, Washington, DC 20503.

During the first 60 days of this same period, a regular review of this information collection is also being undertaken. Comments are encouraged and will be accepted until December 29, 1997. Comments should address one or more of the following four points:

(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.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20530. Additionally, comments may be submitted to OMB via facsimile to 202–395–7285. Comments may also be submitted to the Department of Justice (DOJ), Justice Management Division, Information Management and Security Staff, Attention: Department Clearance Officer, Suite 850, 1001 G Street, NW, Washington, DC 20530. Additionally, comments may be submitted to DOJ via facsimile to 202–514–1534. Written comments may also be submitted to Charlotte C. Grzebien, Associate General Counsel, Office of Community Oriented Policing Services, 1100 Vermont Avenue, NW, Washington, DC 20530, or via facsimile at (202) 514–3456.

Overview of this information collection:

(1) *Type of Information Collection:* New collection.

(2) *Title of the Form/Collection:* Regional Community Policing Institute Monthly Progress Report.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form: COPS 22/01. Office of Community Oriented Policing Services, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Regional Community Policing Institutes funded through a one-year cooperative agreement from the COPS Office are required to respond.

The Regional Community Policing Institute Monthly Progress Report will be completed by each Regional

Community Policing Institute. The information collected provides a monthly update of progress made in performing the training and technical assistance functions of this program, as well as information concerning any changes or modifications requested in the project or cooperative agreement budgets.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* Estimated number of respondents: 35. Estimated time for average respondent to respond: 2 hours and 30 minutes monthly (including record-keeping).

(6) *An estimate of the total public burden (in hours) associated with the collection:* Approximately 1050 annual burden hours.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street NW, Washington, DC 20530.

Dated: October 23, 1997.

**Robert B. Briggs,**

*Department Clearance Officer, United States Department of Justice.*

[FR Doc. 97–28515 Filed 10–27–97; 8:45 am]

BILLING CODE 4410–01–M

## DEPARTMENT OF LABOR

### Office of the Secretary

### Submission for OMB Review; Comment Request

October 23, 1997.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of each individual ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor, Departmental Clearance Officer, Theresa M. O'Malley ({202} 219–5096 ext. 143) or by E-Mail to OMalley-Theresa@dol.gov. Individuals who use a telecommunications device for the deaf (TTY/TDD) may call ({202} 219–4720 between 1:00 p.m. and 4:00 p.m. Eastern time, Monday–Friday.

Comments should be sent to Office of Information and Regulatory Affairs, Attn.: OMB Desk Officer for BLS, DM, ESA, ETA, MSHA, OSHA, PWBA, or VETS, Office of Management and Budget, Room 10235, Washington, DC 20503 ({202}395–7316), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

*Agency:* Mine Safety and Health Administration.

*Title:* Gamma Radiation Exposure Records.

*OMB Number:* 1219–0039 (reinstatement).

*Frequency:* Annually.

*Affected Public:* Business or other for-profit.

*Number of Respondents:* 2.

*Estimated Time Per Respondents:* 1 hour.

*Total Burden Hours:* 2

*Total Annualized capital/startup costs:* 0.

*total annual cost (operating/maintaining systems or purchasing services):* 0.

*Description:* Requires operators of metal and nonmetal underground mines, where radioactive ores are mined, to keep records of the results of annual gamma radiation surveys and individual miner's cumulative gamma radiation exposure.

*Agency:* Employment Standards Administration.

*Title:* Authorization for Release of Medical Information.

*OMB Number:* 1215–0057.

*Agency number:* CM–936.

*Frequency:* One-time.

*Affected Public:* Individuals or households.

*Number of Respondents:* 3,000.

*estimated Time Per Respondent:* 5 minutes.

*Total Burden Hours:* 3,000.

*Total Annualized capital/startup costs:* 0.

*Total annual cost (operating/maintaining systems or purchasing services):* 0.

*Description:* Form CM–936 gives the claimant's consent for the release of medical information covered by the Privacy Act of 1974, and contains information required by medical institutions and private physicians to enable them to release pertinent medical information.

**Theresa M. O'Malley,**

*Departmental Clearance Officer.*

[FR Doc. 97–28504 Filed 10–27–97; 8:45 am]

BILLING CODE 4510–43–M

## DEPARTMENT OF LABOR

### Employment and Training Administration

### Proposed Extension Collection; Comment Request

**ACTION:** Notice.

**SUMMARY:** The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506 (c)(2))A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden will be approximately 10 hours per annual response and we anticipate 56 responses with no capital/start-up costs, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment and Training Administration is soliciting comments concerning the proposed extension collection of the Planning Guidance and Instructions for Submission of Annual State Plans for the Welfare-to-Work Formula Grants.

**ADDRESSES:** U.S. Department of Labor, Employment and Training Administration, ATTENTION: Janice Davis, 200 Constitution Avenue, N.W., Room S–5513, Washington, D.C. 20210, 202–219–0181 extension 155 (this is not a toll free number) and/or via e-mail davisj@doleta.gov; fax number is 202–219–0376.

**SUPPLEMENTARY INFORMATION:**

### I. Background

The Balanced Budget Act of 1997, signed by the President on August 5, 1997, authorized the U.S. Department of

Labor to provide Welfare-to-Work (WtW) Grants to States and local communities to provide transitional employment assistance to move Temporary Assistance for Needy Families (TANF) recipients with significant employment barriers into unsubsidized jobs providing long-term employment opportunities. In order to receive formula grant funds, the statute provides that the State must submit a plan for the administration of the WtW grant. This Planning Guidance and Instructions for Submission of Annual State Plans addresses the information required from States which will enable them to qualify for the formula grant funds. Separate guidance will be issued for both the grants to the Indian tribes and the competitive grants.

**II. Current Actions**

This request has currently been approved under an emergency clearance not to exceed March 31, 1998, this extension is needed in order to complete the collection of this information.

*Type of Review:* Extension.

*Agency:* Employment and Training Administration.

*Title:* Planning Guidance and Instructions for Submission of Annual State Plans for Welfare-to-Work Formula Grants.

*OMB Number:* 1205–0382.

*Affected Public:* State and local governments.

*Total Respondents:* 56.

*Frequency:* Annually.

*Total Responses:* 56.

*Average Time per Response:* 10 hours.

*Estimated Total Burden Hours:* 560.

*Total Burden Cost (capital/startup):* 0.

*Total Burden Cost (operating/maintaining):* 0.

Comments submitted in response to this comment request will be summarized and/or included in the request for the Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Date: October 21, 1997.

**Peter E. Rell,**

*Director, Welfare-to-Work Grant Program Implementation Team.*

[FR Doc. 97–28503 Filed 10–27–97; 8:45 am]

BILLING CODE 4510–30–M

## DEPARTMENT OF LABOR

### Office of the Assistant Secretary for Veterans' Employment and Training,

Secretary of Labor's Advisory Committee for Veterans' Employment and Training; Notice of Open Meeting

The Secretary's Advisory Committee for Veterans' Employment and Training was established under section 4110 of title 38, United States Code, to bring to the attention of the Secretary, problems and issues relating to veterans' employment and training.

Notice if hereby given that the Secretary of Labor's Advisory Committee for Veterans' Employment and Training will meet on Tuesday, December 9, 1997 and December 10, 1997, at the National Veterans' Training Institute (NVTI) in Denver, Colorado from 9:00 a.m. to 4:30 p.m.

Written comments are welcome and may be submitted by addressing them to: Mr. Thomas S. Keefe, Designated Federal Official, Office of the Assistant Secretary for Veterans' Employment and Training, U.S. Department of Labor, 200 Constitution Avenue, NW., Room S–1315, Washington, DC 20210.

The primary items on the agenda are:

- Adoption of minutes of the previous meeting
- Agency Update by Assistant Secretary-designate Espiridion Al Borrego
- Auditing of TAP and Case Management Classes at NVTI
- Discussion of the GAO report on Veterans' Employment and Training—October 1997

The meetings will be open to the public.

Persons with disabilities, needing special accommodations, should contact Mr. Thomas S. Keefe at telephone number 202–219–9105 no later than November 21, 1997.

Signed at Washington, DC this October 22, 1997.

**Espiridion A. Borrego,**

*Acting Assistant Secretary of Labor for Veterans' Employment and Training.*

[FR Doc. 97–28502 Filed 10–27–97; 8:45 am]

BILLING CODE 4510–79–M

## LEGAL SERVICES CORPORATION

### Sunshine Act Meeting of the Board of Directors Finance Committee

**TIME AND DATE:** The Finance Committee of the Legal Services Corporation's Board of Directors will meet on November 14, 1997. The meeting will begin at 10:00 a.m. and continue until conclusion of the committee's agenda.

**LOCATION:** Legal Services Corporation, 750 First Street NE.—10th Floor, Washington, DC 20002.

**STATUS OF MEETING:** Open.

**MATTERS TO BE CONSIDERED:**

1. Approval of agenda.
2. Approval of the minutes of the committee's meeting of September 19, 1997.
3. Review of Corporation's FY '97 budget and expenses through September 30, 1997.
4. Review breakdown of FY 1999 ''budget mark.''
5. Review guidelines for adoption, review and modification of the consolidated operating budget.
6. Review budget timetable, September 1997—January 1999.
7. Consider and act on other business.
8. Public comment.

**CONTACT PERSON FOR INFORMATION:** Victor M. Fortuno, General Counsel and Secretary of the Corporation, at (202) 336–8810.

**SPECIAL NEEDS:** Upon request, meeting notices will be made available in alternate formats to accommodate visual and hearing impairments. Individuals who have a disability and need an accommodation to attend the meeting may notify Jean Edwards at (202) 336–8811.

Dated: October 23, 1997.

**Victor M. Fortuno,**

*General Counsel.*

[FR Doc. 97–28588 Filed 10–23–97; 5:08 pm]

BILLING CODE 7050–01–P

## LEGAL SERVICES CORPORATION

### Sunshine Act Meeting of the Board of Directors

**TIME AND DATE:** The Board of directors of the Legal Services Corporation will meet on November 15, 1997. The meeting will begin at 10:00 a.m. and continue until conclusion of the Board's agenda.

**LOCATION:** Legal Services Corporation, 750 First Street N.E.—10th Floor, Washington, DC 20002.

**STATUS OF MEETING:** Open, except that a portion of the meeting may be closed pursuant to a unanimous vote of the Board of Directors to hold an executive session. At the closed session, the Corporation's General Counsel will report to the Board on litigation to which the corporation is or may become a party, and the Board may act on the matters reported. Also, the Board will consider and act on an internal personnel issue relating to the Corporation's employee pension plan. The closing is authorized by the relevant provisions of the Government in the Sunshine Act [5 U.S.C. 552b(c) (2) & (10)] and the corresponding provision of the Legal Services Corporation's implementing regulation [45 CFR 1622.5 (a) & (h)]. A copy of the General Counsel's Certification that the closing

is authorized by law will be available upon request.

**MATTERS TO BE CONSIDERED:**

Open Session

1. Approval of agenda.
2. Approval of minutes of the Board's meeting of Sept. 20, 1997.
3. Approval of minutes of the Board's executive session meeting of Sept. 20, 1997.
4. Chairman's and Members' Reports.
5. President's Report.
6. Appointment of an *ad hoc* committee for annual performance evaluations of the President and Inspector General.
7. Consider and act on the report of the Board's Operations and Regulations Committee.
   a. Consideration of public comment and action on final revisions to 45 CFR Part 1630, Costs Standards and Procedures.
   b. Consideration of public comment and action on final rule 45 CFR Part 1643, Restriction on Assisted Suicide, Euthanasia and Mercy killing.
   c. Consider and act on proposed changes to the structure of the Corporation's management.
8. Consider and act on the report of the Board's Finance Committee.
9. Consider and act on the report of the *Ad Hoc* Committee on Performance Reviews of the President and Inspector General.
   a. Consider and act on proposed policies and procedures for annual performance reviews of the Corporation's President and Inspector General.
10. Consider and act on report on development of a strategic planning process.
11. Inspector General's Report.

Closed Session

12. Briefing [1] by the Inspector General on the activities of the OIG.
13. Consider and act on an internal personnel issue relating to the Corporation's employee pension plan.
14. Consider and act on the General Counsel's report on potential and pending litigation involving the Corporation.

Open Session

15. Consider and act on whether to change the date of the next annual meeting and, if so, to what date.
16. Public comment.
17. Consider and act on other business.

**CONTACT PERSON FOR INFORMATION:** Victor M. Fortuno, General Counsel and Secretary of the Corporation, at (202) 336–8810.

**SPECIAL NEEDS:** Upon request, meeting notices will be made available in alternate formats to accommodate visual and hearing impairments. Individuals who have a disability and need an accommodation to attend the meeting may notify Ms. Jean Edwards, at (202) 336–8811.

Dated: October 23, 1997.

**Victor M. Fortuno,**

*General Counsel & Secretary of the Corporation.*

[FR Doc. 97–28589 Filed 10–23–97; 5:08 pm]

BILLING CODE 7050–01–P

[1] Any portion of the closed session consisting solely of staff briefings does not fall within the Sunshine Act's definition of the term ''meeting'' and, therefore, the requirements of the Sunshine Act do not apply to any such portion of the closed session. 5 U.S.C. 552(b)(a)(2) and (b). See also 45 CFR § 1622.2 & 1622.3.

## LEGAL SERVICES CORPORATION

### Sunshine Act Meeting of the Board of Directors Ad Hoc Committee on Performance Reviews of the President and Inspector General

**TIME AND DATE:** The Ad Hoc Committee on Performance Reviews of the President and Inspector General of the Legal Services Corporation's Board of Directors will meet on November 14, 1997. The meeting will begin at 2:00 p.m. and continue until conclusion of the committee's agenda.

**LOCATION:** Legal Services Corporation, 750 First Street N.E.—10th Floor, Washington, DC 20002.

**STATUS OF MEETING:** Open.

**MATTERS TO BE CONSIDERED:**

1. Approval of agenda.
2. Approval of the minutes of the committee's meeting of July 13, 1997.
3. Consider and act on procedural matters, including personal performance plans for the President and the Inspector General, written submissions prior to interviews, and interview protocols.
4. Consider and act on other business.
5. Public comment.

**CONTACT PERSON FOR INFORMATION:** Victor M. Fortuno, General Counsel and Secretary of the Corporation, at (202) 336–8810.

**SPECIAL NEEDS:** Upon request, meeting notices will be made available in alternate formats to accommodate visual and hearing impairments. Individuals who have a disability and need an accommodation to attend the meeting may notify Jean Edwards at (202) 336–8811.

Dated: October 23, 1997.

**Victor M. Fortuno,**

*General Counsel.*

[FR Doc. 97–28590 Filed 10–23–97; 5:08 pm]

BILLING CODE 7050–01–P

## LEGAL SERVICES CORPORATION

### Meeting of the Board of Directors Operations and Regulations Committee

*Time and Date:* The Operations and Regulations Committee of the Legal Services Corporation's Board of Directors will meet on November 14, 1997. The meeting will begin at 10:00 a.m. and continue until the committee concludes its agenda.

*Location:* Legal Services Corporation, 750 First Street N.E.—10th Floor, Washington, DC 20002.

*Status of Meeting:* Open.

**MATTERS TO BE CONSIDERED:**

*Open Session*

1. Approval of agenda.
2. Approval of minutes of the committee's meeting of Sept. 19, 1997.
3. Consider public comment and act on final revisions to 45 CFR Part 1630, Costs Standards and Procedures.
4. Consider public comment and act on final rule, 45 CFR Part 1643, Restriction on Assisted Suicide, Euthanasia and Mercykilling.
5. Consider and act on memorandum regarding the status of LSC rulemaking and staff recommendations for FY 1998 rulemaking schedule.
6. Consider and act on proposed changes to the structure of the Corporation's management.
7. Consider and act on other business.

*Contact Person for Information:* Victor M. Fortuno, General Counsel and Secretary of the Corporation, at (202) 336–8810.

*Special Needs:* Upon request, meeting notices will be made available in alternate formats to accommodate visual and hearing impairments. Individuals who have a disability and need an accommodation to attend the meeting may notify Jean Edwards at (202) 336–8811.

October 23, 1997.

**Victor M. Fortuno,**

*General Counsel.*

[FR Doc. 97–28591 Filed 10–23–97; 5:08 pm]

BILLING CODE 7050–01–P

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

**[Notice (98–157)]**

### NASA Advisory Council, Advisory Committee on the International Space Station, Cost Assessment and Validation Task Force on Space Station; 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, Advisory Committee on the International Space Station, Cost Assessment and Validation Task Force on Space Station.

**DATES:** Thursday, November 6, 1997, from 9:00 a.m. until 2:00 p.m.

**ADDRESSES:** MIC–6A, 6th Floor, NASA Headquarters, 300 E Street, SE, Washington, DC 20546.

**FOR FURTHER INFORMATION CONTACT:** Mr. Daniel Hedin, Code ML, National Aeronautics and Space Administration, Washington, DC 20546, 202/358–1691.

**SUPPLEMENTARY INFORMATION:** The meeting will be open to the public up to seating capacity of the room, from 9:00 a.m. until 2:00 p.m. on Thursday, November 6, 1997. The meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

—International Space Station Overview and Status
—International Space Station Budget Overview
—Congressional Perspective

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants. Visitors will be requested to sign a visitor's register.

Dated: October 22, 1997.

**Alan Ladwig,**

*Advisory Committee Management Officer, National Aeronautics and Space Administration.*

[FR Doc. 97–28532 Filed 10–27–97; 8:45 am]

BILLING CODE 7510–01–M

## NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

### National Endowment for the Arts; Federal Advisory Committee on International Exhibitions

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that a meeting of the Federal Advisory Committee on International Exhibitions (FACIE) to the National Council on the Arts will be held on November 17, 1997. The panel will meet from 10:00 a.m. to 4:30 p.m. in Room 716 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, N.W., Washington, D.C. 20506. A portion of this meeting, from 3:30 p.m. to 4:30 p.m., will be open to the public for a policy discussion.

The remaining portion of this meeting, from 10:00 a.m. to 3:30 p.m., is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of March 31, 1997, these sessions will be closed to the public pursuant to subsection (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of AccessAbility, National Endowment for the Arts, 1100 Pennsylvania, N.W., Washington, D.C. 20506, 202/682–5532, TDY–TDD 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Committee Management Officer, National Endowment for the Arts, Washington, D.C. 20506, or call 202/682–5691.

Dated: October 22, 1997.

**Kathy Plowitz-Worden,**

*Panel Coordinator, Panel Operations, National Endowment for the Arts.*

[FR Doc. 97–28469 Filed 10–21–97; 8:45 am]

BILLING CODE 7537–01–M

## NUCLEAR REGULATORY COMMISSION

**[Docket Nos. 50–269, 50–270, and 50–287]**

### Duke Energy Corporation, Oconee Nuclear Station Units 1, 2, and 3; Notice of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of amendments to Facility Operating License Nos. DPR–38, DPR–47, and DPR–55, issued to the Duke Energy Corporation (the licensee), for operation of the Oconee Nuclear Station, Units 1, 2, and 3 located in Oconee County, South Carolina.

If approved, the proposed amendments to the Technical Specifications (TS) would allow use of a rerolling process as an additional repair method for steam generator tube degradation.

Currently, Unit 1 is shut down for its end-of-cycle 17 refueling outage. During a non-destructive examination of the hot leg tubesheet, indications of tube degradation was found in the upper tubesheet region of approximately 900 tubes in the 1B steam generator. The licensee has proposed use of a rerolling process to ensure that the area of degradation will not serve as a pressure boundary once the repair roll is installed, thus, permitting the tube to remain in service. The current TS only allow use of a sleeving process to repair steam generator tubes, otherwise the tubes must be removed from service by plugging. Since the reroll process is not contained in the Oconee TS as an approved repair method, NRC staff approval of the amendments is necessary prior to exceeding 250 °F in the Unit 1 Reactor Coolant System. Unit 1 is presently expected to restart in the third week of November 1997.

Therefore, the amendments must be processed prior to that date. Any delay would delay the startup, which requires that the amendments be processed under exigent circumstances.

Before issuance of the proposed license amendments, 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:

This proposed change has been evaluated against the standards in 10 CFR 50.92 and has been determined to involve no significant hazards, in 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?

No. The implementation of the tube reroll does not increase the probability of occurrence of an accident or the consequences of an accident previously evaluated.

Since reroll utilizes the original tube configuration and extends the roll expanded region, all of the design and operating characteristics of the steam generator and connected systems are preserved. The reroll joint length has been analyzed and tested for design, operating, and faulted condition loadings.

At worst case, a tube leak would occur with the result being a primary to secondary system leak. Should a tube leak occur, the impact is bounded by the ruptured tube evaluation which has been analyzed previously. The potential for a tube rupture is not increased by the use of the reroll process.

2. Create the possibility of a new or different kind of accident from the accidents previously evaluated?

No. Operation of the steam generators with reroll repaired tubes does not create the possibility of a new or different accident from the accidents previously evaluated.

The potential failure of the tube due to the defect which required the tube to initially be repaired is covered during the qualification of the reroll process. Qualification testing indicates that normal and faulted leakage would be well below the Technical Specification limits. Since the normal and faulted leak rates are well within the Technical Specification limit, the analyzed accident scenarios are still bounding.

The new roll transition may eventually develop PWSCC [primary water stress-corrosion cracking] and require additional repair. Since the roll transition is located within the tubesheet, it is not possible for the degradation to result in a tube rupture. Additionally, industry experience with roll transition cracking has shown that PWSCC in roll transitions is normally short axial cracks, with extremely low leak rates. Finally, since the new roll transition is completely within the tubesheet there is no possibility of the repaired tube failing and impacting adjacent tubes.

In the unlikely event the reroll repaired tube failed and severed completely at the transition of the reroll region, the tube would retain engagement in the tubesheet bore, preventing any interaction with neighboring tubes. In this case, leakage is minimized and is well within the assumed leakage of the design basis tube rupture accident. In addition, the possibility of rupturing multiple steam generator tubes is not increased.

3. Involve a significant reduction in a margin of safety?

No. Based on the previous response, the protective boundaries of the steam generator are preserved.

A tube with degradation can be kept in service through the use of the reroll process. The new undegraded roll expanded interface created with the tubesheet satisfies all of the necessary structural, leakage, and heat transfer requirements. Since the joint is constrained within the tubesheet bore, there is no additional risk associated with tube rupture. Therefore, the analyzed accident scenarios remain bounding, and the use of the reroll process does not reduce the margin of safety.

Duke has concluded based on the above information that there are no significant hazards involved in this amendment request.

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 14 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 14-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 derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 14-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. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 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 28, 1997, 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 Oconee County Library, 501 West South Broad Street, Walhalla, South Carolina. 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 a 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 two weeks 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 the amendment is issued before the expiration of the 30-day hearing period, the Commission will make a final determination on the issue of no significant hazards consideration. If a hearing is requested, 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 20555–0001, Attention: Rulemaking and Adjudications Staff, may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and to M. J. Michael McGarry, III, Winston and Strawn, 1200 17th Street, NW., Washington, DC 20036, 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 amendments dated October 20, 1997, 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 Oconee County Library, 501 West South Broad Street, Walhalla, South Carolina.

Dated at Rockville, Maryland, this 22nd day of October 1997.

For the Nuclear Regulatory Commission.

**David E. LaBarge,**

*Senior Project Manager, Project Directorate II–2, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.*

[FR Doc. 97–28529 Filed 10–27–97; 8:45 am]

BILLING CODE 7590–01–P

## NUCLEAR REGULATORY COMMISSION

**[Docket No. 50–416]**

## Entergy Operations, Inc., System Energy Resources, Inc., South Mississippi Electric Power Association, Entergy Mississippi, Inc.; Grand Gulf Nuclear Station, Unit 1; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC or the Commission) is considering the issuance of an exemption to Facility Operating License No. NPF–29, which was issued to Entergy Operations, Inc. (the licensee), for operation of the Grand Gulf Nuclear Station, Unit 1, (GGNS) located in Claiborne County, Mississippi.

### Environmental Assessment

*Identification of the Proposed Action*

The proposed action would exempt the licensee from the criticality monitoring requirement in 10 CFR 70.24(a), ''Criticality Accident Requirements,'' which requires a monitoring system that will energize clear audible alarms if accidental criticality occurs in each area in which special nuclear material (SNM) is handled, used, or stored. The proposed action is for monitoring the storage of SNM in the form of (1) not-in-use in-core nuclear instrumentation (e.g., source range monitors), which contain very small quantities of SNM, and (2) unirradiated fuel. For the unirradiated fuel, the exemption is requested for the unirradiated fuel that is packaged in accordance with 10 CFR Part 71, ''Packaging and Transportation of Radioactive Material,'' while the fuel is onsite and taken from the shipping trucks to the spent fuel pool area to be removed from the packaging, and the unirradiated fuel that is stored in the new fuel vault. The unirradiated fuel that would be stored in the spent fuel pool would have the required 70.24(a) criticality accident monitoring system.

The proposed action is in accordance with the licensee's application dated July 15, 1996, as supplemented by the letters dated March 7 and April 29, 1997.

*The Need for the Proposed Action*

The proposed action would allow the licensee an exemption from the requirement to provide criticality accident monitoring for the above two forms of SNM, listed in its application, while the forms are being stored at the site within the security fence in different plant areas (in-core nuclear

instrumentation), or in the new fuel vault (unirradiated fuel), or while the unirradiated fuel is being transferred from shipping trucks to the spent fuel pool area to be removed from the Part 71 packaging.

The licensee stated that compliance to the criticality accident monitoring system requirements of 10 CFR 70.24(a) would result in a considerable expenditure of resources to install, maintain and operate a criticality monitoring system for the storage of the two forms of SNM, and there should be no concern about criticality ever occurring with the two forms of SNM as they are being stored onsite. There is too small a quantity of SNM, in the form of very thin coatings, present in the nuclear instrumentation for criticality, and unirradiated fuel assemblies would only be removed from the NRC-approved (i.e., Part 71) packaging before being stored in the spent fuel pool where criticality monitors are in use, or in the new fuel vault where there are no criticality monitors.

In the new fuel vault, the unirradiated fuel would be stored in racks which are designed, as Safety Class 2 and Seismic Category I, to withstand all credible loadings to prevent damage and distortion of the racks, and to keep the subcriticality margin of at least 0.95 whether the vault is dry or flooded with water. The new fuel vault is in a concrete, Seismic Category I building that is designed to preclude the deleterious effects on the fuel by natural phenomena such as earthquakes, tornados, hurricanes, tornado missiles and floods.

The Part 71 package design ensures that a geometrically safe configuration for the fuel is maintained during transport, handling, storage and accident conditions, and precludes introduction of any moderating agents due to leak-tight construction, and; therefore, criticality is precluded due to the construction of the package and the storage configuration of the fuel in the package.

*Environmental Impacts of the Proposed Action*

The Commission has completed its evaluation of the proposed action and concludes that there is no significant environmental impacts if the exemption is granted. Inadvertent or accidental criticality will be precluded through compliance with the Technical Specifications (TS), the design of the fuel storage racks providing geometric spacing of unirradiated fuel assemblies in their storage locations, and administrative controls imposed on fuel handling procedures and the in-core nuclear instrumentation. TS requirements specify reactivity limits for the fuel storage racks and minimum spacing between the fuel assemblies in the storage racks.

The proposed exemption to 10 CFR 70.24(a) does not affect the design or operation of the plant, does not involve any modifications to the plant or any increase in the licensed power for the plant, and will not create any new or unreviewed environmental impacts that were not considered in the Final Environmental Statement (FES) related to the operation of GGNS, NUREG–0777, dated September 1981. The proposed action will not increase the probability or consequences of any accidents. No changes are being made to any structure, system, or component in the plant, to how the plant is operated, in the types or amounts of any effluents that may be released offsite, and in the allowable individual or cumulative occupational radiation exposure for the plant. The amount of radioactive waste would not be changed by the proposed exemption. Accordingly, the Commission concludes that the proposed exemption would not result in any significant radiological impacts.

With regard to potential nonradiological impacts, the proposed action involves features located entirely within the restricted area as defined in 10 CFR Part 20. It does not affect the nonradiological plant effluents and has no other environmental impact. Accordingly, the Commission concludes that there are no significant nonradiological environmental impacts associated with the proposed action.

*Alternatives to the Proposed Actions*

Since the Commission has concluded there is no measurable environmental impact associated with the proposed action, any alternatives with equal or greater environmental impact need not be evaluated.

As an alternative to the proposed action, the staff considered denial of the proposed action. Denial of the request would result in no change in current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

*Alternative Use of Resources*

This action does not involve the use of any resources not previously considered in the FES for the GGNS.

*Agencies and Persons Consulted*

In accordance with its stated policy, on October 20, 1997, the staff consulted with the Mississippi State official, Robert Goff of the Division of Radiological Health, State Board of Health, regarding the environmental impact of the proposed action. The State official had no comments.

**Finding of No Significant Impact**

Based upon the environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letters dated July 15, 1996, March 7 and April 29, 1997, which 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 Judge George W. Armstrong Library, 220 S. Commerce Street, Natchez, Mississippi 39120.

Dated at Rockville, Maryland, this 21st day of October, 1997.

For the Nuclear Regulatory Commission.

**David L. Wigginton,**

*Acting Director, Project Directorate IV–1, Division of Reactor Projects III/IV, Office of Nuclear Reactor Regulation.*

[FR Doc. 97–28531 Filed 10–27–97; 8:45 am]

BILLING CODE 7590–01–P

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## NUCLEAR REGULATORY COMMISSION.

**[Docket No. 40–1162]**

## Western Nuclear, Inc.; Final Finding of No Significant Impact; Notice of Opportunity for Hearing

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) proposes to amend NRC Source Material License SUA–56, issued to Western Nuclear, Inc. (WNI), by removing reference to the Day Loma uranium heap leach site. To document its review of the potential environmental impacts associated with the proposed action, the NRC staff prepared an Environmental Assessment in accordance with the requirements of 10 CFR Part 51. The conclusion of the Environmental Assessment is a Finding of No Significant Impact (FONSI) for the proposed licensing action.

**FOR FURTHER INFORMATION CONTACT:** Mr. Robert D. Carlson of the Uranium Recovery Branch, Mail Stop TWFN 7–J9, Division of Waste Management, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone 301/415–8165.

**SUPPLEMENTARY INFORMATION:**

## Background

The Day Loma uranium heap leach site is located approximately 40 kilometers (25 miles) northeast of Jeffrey City, Wyoming, in an area known as the Gas Hills Region. This 14,975-hectare (37,000-acre) region is rich in naturally occurring deposits of uranium ore, and widespread uranium mining activity occurred in the region from the late 1950s until the 1980s.

Source Material License SUA–582, which covered activities at the Day Loma site, was originally issued to WNI in 1962. Operations at the site terminated in 1972, and in 1976, SUA–582 was combined with Source Material License SUA–56 for WNI's Split Rock uranium mill. Currently, the Day Loma site is licensed by the NRC under SUA–56 for possession only of byproduct material in the form of heap leach waste from the processing of uranium ore generated from past mining operations.

The NRC approved WNI's reclamation plan for the Day Loma site in 1981, and WNI completed reclamation activities at the site in 1985. The NRC staff inspected and approved the completion of the reclamation work in August 1986. The reclaimed leached material, consisting of approximately 494,000 tons of low-grade (less than 0.05 percent) uranium-bearing rock, was placed on an impervious liner that was constructed on top of existing uranium spoil materials comprised of overburden and mine waste. Following recontouring, a final disposal cell cover of between 2.4 and 4.0 meters (8 and 13 feet) in thickness was constructed of clay and random fill material. The 6.3 ha (15.6 acre) reclaimed site is surrounded by exposed mine spoils unreclaimed mining lands of the Gas Hills Region.

By letter dated October 19, 1995, WNI requested that all reference to the Day Loma site be removed from SUA–56, thereby ending current monitoring and the need for long-term monitoring of the site. A consequence of granting the proposal will be to not require transfer of the Day Loma site to Federal or State ownership as authorized by Section 83b.(4) of the Atomic Energy Act of 1954, as amended.

The State of Wyoming Department of Environmental Quality (WDEQ) will be performing substantial reclamation operations in the Day Loma site area over the next five years in an effort to return this area to its original pre-mining condition. The WDEQ plans to incorporate the heap leach site into its reclamation efforts by recontouring the site into the surrounding landscape.

## Conclusions

The NRC staff has evaluated the environmental impacts associated with the removal of reference to the Day Loma site from Source Material License SUA–56, and has determined that approval of the proposed action (1) will be consistent with requirements of 10 CFR Part 40, (2) will not be deleterious to public health and safety, and (3) will not have long-term detrimental impacts on the environment. The following statements support the FONSI and summarize the conclusions resulting from the staff's environmental assessment:

1. The Gas Hills Region is sparsely populated and likely to remain so indefinitely, as the climate is harsh, the land is relatively barren, and the groundwater in the region is considered of such poor quality that it is deemed unsuitable for either domestic or agricultural use;

2. Using conservative assumptions in which the Day Loma heap leach material was assumed to have no radon cover, the NRC staff showed that potential doses to members of the public from the heap leach site and associated risk factors for public health and the environment are much less (0.34 mrem/yr) than the 10 CFR Part 20 public dose limit of 100 mrem/yr and those resulting from the naturally occurring uranium ore deposits which surround the site (34 mrem/yr);

3. The WDEQ will incorporate the heap leach site in its efforts to further reclaim existing mine spoils in the Day Loma area over the next five years; and

4. The staff has determined there will be no significant impacts associated with approval of the amendment request, and accordingly no disproportionately high and adverse effects or impacts on minority and low-income populations. Except in special cases, these impacts need not be addressed for Environmental Assessments in which a FONSI is made. Special cases may include regulatory actions that have substantial public interest, decommissioning involving on-site disposal in accordance with 10 CFR 20.2002, decommissioning/decontamination cases which allow residual radioactivity in excess of release criteria, or cases where environmental justice issues have been raised previously. Consequently, further evaluation of 'Environmental Justice' concerns, as outlined in Executive Order 12898 and NRC's Office of Nuclear Material Safety and Safeguards Policy and Procedures Letter 1–50, Rev.1, is not warranted.

In conducting its evaluation, the NRC staff considered the following: (1) information and analyses provided by WNI as part of its license amendment request; (2) additional analyses conducted by the NRC staff; and (3) information derived from NRC staff communications with the WDEQ.

## Alternatives to the Proposed Action

The proposed action is to amend NRC Source Material License SUA–56, by removing reference to the Day Loma uranium heap leach site, as requested by WNI. Therefore, the alternatives available to NRC are to:

(1) Approve the license amendment request as submitted by WNI;

(2) Approve the license amendment request with such conditions as are considered necessary or appropriate to protect public health and safety and the environment; or

(3) Deny the license amendment request.

Based on its review, the NRC staff has concluded that there are no significant environmental impacts associated with the proposed action; therefore, any alternatives with equal or greater environmental impacts need not be evaluated. Since the environmental impacts of the proposed action and the other two alternatives are similar, there is no need to further evaluate alternatives to the proposed action.

## Finding of No Significant Impact

The NRC staff has prepared an Environmental Assessment for the proposed amendment of NRC Source Material License SUA–56. On the basis of this assessment, the NRC staff has concluded that the environmental impacts that may result from the proposed action would not be significant, and therefore, preparation of an Environmental Impact Statement is not warranted.

The Environmental Assessment and other documents related to this proposed action are available for public inspection and copying at the NRC Public Document Room, in the Gelman Building, 2120 L Street N.W., Washington, DC 20555.

## Notice of Opportunity for Hearing

The Commission hereby provides notice that this is a proceeding on an application for a licensing action falling within the scope of Subpart L, ''Informal Hearing Procedures for Adjudications in Materials and Operator Licensing Proceedings,'' of the Commission's Rules of Practice for Domestic Licensing Proceedings in 10 CFR Part 2 (54 FR 8269). Pursuant to § 2.1205(a), any person whose interest may be affected

by this proceeding may file a request for a hearing with respect to the technical evaluation and the Environmental Assessment performed by the NRC staff that forms the basis for the decision to amend the license and remove reference to the Day Loma heap leach site from Source Material License SUA–56. In accordance with § 2.1205(c), a request for a hearing must be filed within thirty (30) days from the date of publication of this **Federal Register** notice. The request for a hearing must be filed with the Office of the Secretary either:

(1) By delivery to the Docketing and Service Branch of the Office of the Secretary at One White Flint North, 11555 Rockville Pike, Rockville, MD 20852; or

(2) By mail or telegram addressed to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Each request for a hearing must also be served by delivering it personally or by mail to:

(1) The applicant, Western Nuclear, Inc., 200 Union Blvd., Suite 300, Lakewood, Colorado, 80228;

(2) The NRC staff, by delivery to the Executive Director of Operations, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852; or

(3) By mail addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

In addition to meeting other applicable requirements of 10 CFR Part 2 of the Commission's regulations, a request for a hearing filed by a person other than an applicant must describe in detail:

(1) The interest of the requestor in the proceeding;

(2) How that interest may be affected by the results of the proceeding, including the reasons why the requestor should be permitted a hearing, with particular reference to the factors set out in § 2.1205(g);

(3) the requestor's areas of concern about the licensing activity that is the subject matter of the proceeding; and

(4) The circumstances establishing that the request for a hearing is timely in accordance with § 2.1205(c).

Any hearing that is requested and granted will be held in accordance with the Commission's ''Informal Hearing Procedures for Adjudications in Materials and Operator Licensing Proceedings'' in 10 CFR Part 2, Subpart L.

Dated at Rockville, Maryland, this 22nd day of October 1997.

For the Nuclear Regulatory Commission.

**Joseph J. Holonich,**

*Chief, Uranium Recovery Branch, Division of Waste Management, Office of Nuclear Material, Safety and Safeguards.*

[FR Doc. 97–28530 Filed 10–27–97; 8:45 am]

BILLING CODE 7590–01–P

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## NUCLEAR REGULATORY COMMISSION

### Sunshine Act Meeting

**AGENCY HOLDING THE MEETING:** Nuclear Regulatory Commission.

**DATE:** Weeks of October 27, November 3, 10, and 17, 1997.

**PLACE:** Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

**STATUS:** Public and Closed.

**MATTERS TO BE CONSIDERED:**

*Week of October 27*

Wednesday, October 29

11:30 a.m. Affirmation Session (PUBLIC MEETING) (if needed)

2:00 p.m. Briefing on Site Decommissioning Management Plan (SDMP) (PUBLIC MEETING) (Contact: John Hickey—301–415–7234)

Thursday, October 30

10:30 a.m. and 1:30 p.m. All Employees meetings (PUBLIC MEETING) on ''The Green'' Plaza Area between buildings at White Flint (Contact: Bill Hill—301–415–1661)

*Week of November 3*

Tuesday, November 4

10:00 a.m. Briefing by the Executive Branch (Closed—Ex. 1)

2:00 p.m. Meeting with Commonwealth Edison (PUBLIC MEETING) (Contact: Bob Capra—301–415–1395)

Wednesday, November 5

9:30 a.m. Briefing on Staff's Plans for 50.59 Regulatory Process Improvements (PUBLIC MEETING) (Contact: Eileen McKenna—301–415–2189)

11:00 a.m. Affirmation Session (PUBLIC MEETING) (if needed)

*Week of November 10—Tentative*

There are no meetings the week of November 10.

*Week of November 17—Tentative*

Friday, November 21

11:30 a.m. Affirmation Session (PUBLIC MEETING) (If needed)

**Note:** The Schedule for commission meetings is subject to change on short notice. To verify the status of meeting call (Recording)—(301) 415–1292.

**CONTACT PERSON FOR MORE INFORMATION:** Bill Hill (301) 415–1661.

The NRC Commission Meeting Schedule can be found on the Internet at: http://www.nrcgov/SECY/smj/schedule.htm.

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 (301–415–1661).

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 wmhnrc.gov or dkwnrc.gov.

Dated: October 24, 1997.

**William M. Hill, Jr.,**

*Secy Tracking Officer, Office of the Secretary.*

[FR Doc. 97–28681 Filed 10–24–97; 2:45 pm]

BILLING CODE 2590–01–M

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## NUCLEAR REGULATORY COMMISSION

**[Docket No. 72–18]**

### Prairie Island Offsite Independent Spent Fuel Storage Installation; Closing of Temporary Local Public Document Room

Notice is hereby given that the Nuclear Regulatory Commission (NRC) will consider the temporary local public document room (LPDR) set up for records pertaining to Northern States Power Company's proposed Prairie Island Offsite Independent Spent Fuel Storage Installation (ISFSI), located at the Red Wing Public Library, Red Wing, Minnesota, officially closed effective October 31, 1997. The NRC's official full service LPDR for the Prairie Island Nuclear Station, located at the Minneapolis Public Library, 300 Nicollet Mall, Minneapolis, Minnesota, will remain operational.

Dated at Rockville, Maryland, this 22 day of October, 1997.

For the Nuclear Regulatory Commission.

**Russell A. Powell,**

*Chief, Freedom of Information/Local, Public Document Room Branch, Office of Information Resources Management.*

[FR Doc. 97–28528 Filed 10–27–97; 8:45 am]

BILLING CODE 7590–01–P

## NUCLEAR REGULATORY COMMISSION

**[Docket Nos. 50–245, 50–336, 50–423 and 50–213]**

### Northeast Utilities, Millstone Nuclear Power Station, Units 1, 2, and 3; Haddam Neck Plant; Correction to Partial Director's Decision Under 10 CFR 2.790

On September 12, 1997, the Commission issued a Partial Director's Decision (DD–97–21) in response to a 10 CFR 2.206 Petition submitted by the Citizens Awareness Network and the Nuclear Information and Resource Service. Due to an administrative error, items (4) and (5) in Section 1., INTRODUCTION, of the Director's Decision were inadvertently interchanged.

Correction is being made to the Thursday, September 18, 1997, **Federal Register** publication as follows: page 49035, first column, first full paragraph, item (4) should be marked as item ''(5)'' and item (5) should be marked as item ''(4).''

Dated at Rockville, Maryland, this 20th day of October 1997.

For the Nuclear Regulatory Commission.

**Daniel G. McDonald Jr.,**

*Senior Project Manager, Special Projects Office—Licensing, Office of Nuclear Reactor Regulation.*

[FR Doc. 97–28527 Filed 10–27–97; 8:45 am]

BILLING CODE 7590–01–M

## OFFICE OF PERSONNEL MANAGEMENT

### Proposed Collection, Comment Request; Standard Form 87 and 87A

**AGENCY:** Office of Personnel Management.

**ACTION:** Proposed collection; comment request.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, May 22, 1995), this notice announces that the Office of Personnel Management (OPM) intends to submit to the Office of Management and Budget (OMB) a request for reclearance of an information collection.

The Standard Form 87 and 87A Fingerprint Charts are completed by applicants for positions throughout the Federal Government. SF 87 is used by OPM, and SF 87A is used by agencies having a special agreement with OPM and the FBI. The information is used to conduct the checks of the FBI fingerprint files that are required by Executive Order 10450, Security Requirements for Government Employment issued April 27, 1953, or required or authorized under other authorities.

''Comments are particularly invited on:

—Whether this collection of information is necessary for the proper performance of functions of the Office of Personnel Management, and whether it will have practical utility;

—Whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; and

—Ways in which we can minimize the burden of collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.''

**DATES:** Comments on this proposal should be received within 60 calendar days from the date of this publication. Submit comments on this proposal to Richard A. Ferris, Office of Personnel Management, Room 5416, 1900 E. Street NW, Washington, DC 20415.

Office of Personnel Management.

**Janice R. Lachance,**

*Acting Director.*

[FR Doc. 97–28435 Filed 10–27–97; 8:45 am]

BILLING CODE 6325–01–M

## POSTAL SERVICE

### Revised Publication 401, Guide to Manifest Mailing System

**AGENCY:** Postal Service.

**ACTION:** Notice.

**SUMMARY:** This notice adopts revisions to the Postal Service's Publication 401, Guide to the Manifest Mailing System.

**EFFECTIVE DATE:** December 1997.

**FOR FURTHER INFORMATION CONTACT:** Tom Amonette, (202) 268–6258.

**SUPPLEMENTARY INFORMATION:** On July 8, 1997 the Postal Service published in the **Federal Register** proposed revisions to Publication 401, Guide to the Manifest Mailing System (62 FR 36585). These revisions update and reflect changes that have taken place in the past 4 years since the last revision of Publication 401 that affect the submission and acceptance of manifest mailings.

The deadline for submitting comments on the proposed revisions was August 7, 1997. All comments received or mailed by that date have been considered.

**Evaluation of Comments Received**

There was only one written response to the proposed revisions. The commenter addressed two of the proposed revisions. First, they welcomed the change for evaluating the accuracy of Standard Mail (A) piece/pound rate manifest mailings. They agreed that the postage-based comparison will be more accurate than the previous weight-based comparison.

The second comment dealt with the revision that eliminates adjusting postage downwards if the accuracy level determined as a result of sampling by the verifying post office is lower than −1.5%. The commenter believes that this would adversely impact mailers of Standard Mail (A) piece/pound rate mailings because scale tolerance limits for these lighter weight pieces may cause a need for frequent adjustments.

Postage sampling results are a measure of the accuracy of a manifest mailing system. Frequent adjustments indicate that a system is not meeting standards, even if those adjustments are caused by scale tolerance limits. Frequent adjustments increase administrative costs for these systems for the mailer and the Postal Service.

Most mailers who have a problem with weight tolerances due to the type of scales they use have chosen to include a weight factor that automatically prevents underpaying postage and prevents the type of frequent postage adjustments being eliminated. Also, the change to postage-based comparison sampling procedures will make postage sampling more accurate. This should eliminate most errors caused by differences in scale tolerances.

Given these two approaches, the Postal Service does not believe this revision will have an adverse impact on manifest mailers. Also, as stated in the previous notice, if a normally accurate system fails, and it can be shown why overpayment occurred, postage refunds will be considered on a case-by-case basis by the administering rates and classification service center.

The Postal Service will adopt the Publication 401 revisions as proposed. These revisions will go into effect with the printing and public release of this document which is scheduled for December 1997.

**Stanley F. Mires,**

*Chief Counsel, Legislative.*

[FR Doc. 97–28526 Filed 10–27–97; 8:45 am]

BILLING CODE 7710–12–P

## 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, D.C. 20549

Extension:
Rule 17Ad–16, SEC File No. 270–363, OMB Control No. 3235–0413

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 soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

**Rule 17Ad–16 Notice of Assumption or Termination of Transfer Agent Services**

Rule 17Ad–16 under the Securities Exchange Act of 1934, requires a registered transfer agent to provide written notice to a qualified registered securities depository when assuming or terminating transfer agent services on behalf of an issuer or when changing its name or address. These recordkeeping requirements address the problem of certificate transfer delays caused by transfer requests that are directed to the wrong transfer agent or the wrong address.

Approximately 450 transfer agents submit Rule 17Ad–16 notices, the staff estimates that the average number of hours necessary for each transfer agent to comply with Rule 17Ad–16 is approximately 15 minutes per notice or 3.5 hours per year, totalling 1,575 hours industry-wide. The average cost per hour is approximately $30 per hour, with the industry-wide cost estimated at approximately $47,250. However, the information required by Rule 17Ad–16 generally is maintained by registered transfer agents. The amount of time devoted to compliance with Rule 17Ad–16 varies according to differences in business activity.

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 will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information 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.

Please direct your written comments to Michael E. Bartell, Associate Executive Director, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, N.W. Washington, DC 20549.

Dated: October 10, 1997.

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 97–28438 Filed 10–27–97; 8:45 am]

BILLING CODE 8010–01–M

## SOCIAL SECURITY ADMINISTRATION

### Statement of Organization, Functions and Delegations of Authority

This statement amends part T of the Statement of the Organization, Functions and Delegations of Authority which covers the Social Security Administration (SSA). Chapter TA covers the Office of the Deputy Commissioner for Programs and Policy. Notice is hereby given that Subchapter TAH, Office of Hearings and Appeals, is being amended to reflect changes in the organizational designations and functional responsibilities in the Office of Hearings and Appeals, Office of Management. The changes are as follows: Section TAH.10 The Office of Hearings and Appeals—(Organization):

H. The Office of Management (TAHE). Abolish:

5. The Division of Systems Resources (TAHE5) Establish:

5. Office Automation Support Staff (TAHE7) Section TAH.20 The Office of Hearings and Appeals—Functions:

H. The Office of Management (TAHE).

Delete from the first sentence ''systems'' and replace with ''office automation support''.

Delete from the second sentence ''systems'' and replace with ''office automation''.

Delete in its entirety:

5. The Division of Systems Resources (TAHE5). Establish:

5. The Office Automation Support Staff (TAHE7). Provides office automation support to all Office of Hearings and Appeals (OHA) components. Serves as liaison between the Office of Systems (OS), SSA and the OHA end-user community in identifying operational requirements and implementation of applications developed by OS. Manages OHA Automated Data Processing (ADP) resource allocations and directs the operations of the Model Hearing Office. Provides logistical support to OS during the implementation of new applications and technology. Administers the OHA systems security programs. Maintains the local networks located in OHA Headquarters and provides support to the end-users. Manages the OHA Information Technology Systems (ITS) small purchase budget allocated to OHA by OS and provides input to and cost benefit analysis for the budget submission. Maintains the OHA ITS inventory and provides updates to the SSA inventory maintained by OS. Develops and conducts end-user training and arranges for the delivery of appropriate training. Maintains liaison with OHA regional systems staffs and Headquarters staffs for the purpose of identifying operational problems or needs and makes recommendations to OS to resolve outstanding issues.

Dated: September 22, 1997.

**Paul D. Barnes,**

*Deputy Commissioner for Human Resources.*

[FR Doc. 97–28495 Filed 10–27–97; 8:45 am]

BILLING CODE 4190–29–P

## DEPARTMENT OF STATE

**[Public Notice No. 2623]**

### Shipping Coordinating Committee Subcommittee on Standards of Training and Watchkeeping; Notice of Meeting

The Shipping Coordinating Committee (SHC) will conduct an open meeting at 9:30 AM on Wednesday, December 3, 1997, in Room 6319 of the United States Coast Guard Headquarters Building, 2100 2nd Street SW., Washington, DC 20593–0001. The primary purpose of the meeting is to prepare for the twenty-ninth session of the International Maritime Organization (IMO) Sub-Committee on Standards of Training and Watchkeeping (STW) to be held at IMO from January 12 to 16, 1998. Preparations for the Joint IMO/ILO Working Group on Standard format for work hour records, which will be held at IMO from January 19 to 23, 1998, will also be discussed.

The primary matters to be considered include:

1. Review of IMO guidance on principles of safe manning (i.e., crew size);

2. Work emanating from the 1995 Conference of Parties to the International Convention on Standards

of Training, Certification and Watchkeeping (STCW), including consideration of training requirements for maritime pilots;

3. Maritime safety training for personnel on Mobile Offshore Units (MOU/MODUs);

4. Bulk carrier safety;

5. Training record books; and

6. Guidance associated with the International Convention on Standards of Training, Certification and Watchkeeping for Fishing Vessel Personnel (STCW–F Convention, as adopted by the 1995 conference; not yet ratified or in force).

Members of the public may attend the meeting up to the seating capacity of the room. Interested persons may seek information by writing: Mr. Christopher Young, U.S. Coast Guard (G–MOS–1), Room 1210, 2100 Second Street SW., Washington, DC 20593–0001 or by calling: (202) 267–0229.

Dated: October 16, 1997.

**Stephen M. Miller,**

*Executive Secretary, Shipping Coordinating Committee.*

[FR Doc. 97–28511 Filed 10–27–97; 8:45 am]

BILLING CODE 4710–07–M

## OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

**[Docket No. 301–115]**

## Initiation of Section 302 Investigation and Request for Public Comment: Korean Barriers to Auto Imports

**AGENCY:** Office of the United States Trade Representative.

**ACTION:** Notice of initiation of investigation; request for written comments.

**SUMMARY:** The United States Trade Representative (USTR) has initiated an investigation under section 302(b)(1)(A) of the Trade Act of 1974, as amended (the Trade Act), with respect to certain acts, policies and practices of the Government of the Republic of Korea that pose barriers to imports of U.S. autos into the Korean market. USTR invites written comments on the matters being investigated.

**DATES:** This investigation was initiated on October 20, 1997. Written comments from interested persons are due on or before noon on Tuesday, December 2, 1997.

**ADDRESSES:** Office of the United States Trade Representative, 600 17th Street, NW, Washington, DC 20508.

**FOR FURTHER INFORMATION CONTACT:** Sean Murphy, Office of Asia and the Pacific, (202) 395–6813, or Geralyn Ritter, Office of the General Counsel, (202) 395–6800.

**SUPPLEMENTARY INFORMATION:** Executive Order No. 12901 of March 3, 1994, as extended by Executive Order No. 12973 of September 27, 1995, regarding the ''Super 301'' annual review, provides for the USTR to identify priority foreign country practices, the elimination of which is likely to have the most significant potential to increase United States exports, either directly or through the establishment of a beneficial precedent. Accordingly, on October 1, 1997, the USTR identified as a ''priority foreign country practice'' the Government of the Republic of Korea's barriers to auto imports. (See 62 FR 52604 of October 8, 1997). Specific Korean practices of concern include an array of cumulative tariff and tax disincentives that disproportionately affect imports, onerous and costly auto standards and certification procedures, auto financing restrictions, and a climate of bias against imported vehicles that Korean officials have not effectively addressed. While some of these barriers were addressed in a 1995 bilateral agreement between the United States and Korea, implementation of that agreement has been disappointing, especially as new practices have been introduced that undermine the 1995 agreement. Furthermore, imported passenger vehicles continue to represent less than one percent of the Korean market. Although some progress was made during recent bilateral negotiations to improve market access in Korea for foreign automobiles, Korea was not prepared to undertake the reforms which are necessary for real opening of its autos market.

### Investigation and Consultations

Executive Order No. 12901 requires the USTR to initiate an investigation, pursuant to section 302(b)(1)(A) of the Trade Act, of any ''priority foreign country practices.'' On October 20, 1997, the USTR initiated an investigation with respect to certain acts, policies and practices of the Government of the Republic of Korea that pose barriers to imports of U.S. autos into the Korean market. Pursuant to section 303(a) of the Trade Act, the USTR will seek consultations with the Government of Korea concerning the issues under investigation. USTR will seek information and advice from the appropriate representatives provided for under section 135 of the Trade Act in preparing the U.S. presentations for such consultations.

### Public Comment: Requirements for Submissions

Interested persons are invited to submit written comments on the acts, policies and practices of the Government of Korea that are the subject of this investigation, including the amount of burden or restriction on U.S. commerce caused by these acts, policies and practices, and the determinations required under section 304 of the Trade Act regarding whether they are actionable under section 301 and, if affirmative, the appropriate action to take in response.

Comments must be filed in accordance with the requirements set forth in 15 CFR § 2006.8(b) and are due no later than noon on Tuesday, December 2, 1997. Comments must be in English and provided in twenty copies to: Office of the General Counsel, Attn: Korea Auto Investigation, Room 223, USTR, 600 17th Street, NW, Washington, DC 20508.

Comments will be placed in a file (Docket 301–115) open to public inspection pursuant to 15 CFR 2006.13, except confidential business information exempt from public inspection in accordance with 15 CFR 2006.15. Confidential business information submitted in accordance with 15 CFR 1006.15 must be clearly marked ''BUSINESS CONFIDENTIAL'' in a contrasting color ink at the top of each page on each of 20 copies, and must be a accompanied by a nonconfidential summary of the confidential information. The Nonconfidential summary shall be placed in the file that is open to public inspection. An appointment to review the docket (Docket No. 301–115) may be made by calling Brenda Webb (202) 395–6186. The USTR Reading Room is open to the public from 9:30 a.m. to 12 noon and 1:00 p.m. to 4:00 p.m., Monday through Friday, and is located in Room 101.

**Irving A. Williamson,**

*Chairman, Section 301 Committee.*

[FR Doc. 97–28434 Filed 10–27–97; 8:45 am]

BILLING CODE 3190–01–M

## DEPARTMENT OF THE TREASURY

## Submission for OMB Review; Comment Request

September 21, 1997.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Pub. L. 104–13. Copies of the submission(s)

may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

**Bureau of The Public Debt (BPD)**

*OMB Number:* 1535–0009.
*Form Number:* PD F 1851.
*Type of Review:* Extension.
*Title:* Request for Reissue of United States Savings Bonds/Notes in the Name of Trustee or Personal Trust Estate.
*Description:* The form is used to request reissue savings bonds/notes in the name(s) of the trustee(s) of a personal trust estate.
*Respondents:* Individuals or households.
*Estimated Number of Respondents:* 55,000.
*Estimated Burden Hours Per Response:* 30 minutes.
*Frequency of Response:* On occasion.
*Estimated Total Reporting Burden:* 13,750 hours.

*OMB Number:* 1535–0068.
*Form Number:* None.
*Type of Review:* Extension.
*Title:* Regulations Governing Book-Entry Treasury Bonds, Notes and Bills.
*Description:* The information is requested to establish an investor's Treasury Account; to dispose of securities upon the owner's request; and, to determine entitlement securities.
*Respondents:* Individuals or households, Business or other for-profit; Not-for-profit institutions, State, Local or Tribal Government.
*Estimated Number of Respondents:* 75,000.
*Estimated Burden Hours Per Response:* 7 minutes.
*Frequency of Response:* On occasion.
*Estimated Total Reporting Burden:* 8,775 hours.

*OMB Number:* 1535–0087.
*Form Number:* None.
*Type of Review:* Extension.
*Title:* Payment by Banks and Other Financial Institutions of United States Savings Bonds and Notes (Freedom Shares).
*Description:* Qualified financial institutions are authorized to redeem eligible savings bonds and notes, and receive settlement through the Federal Reserve check collection system.
*Respondents:* Business or other for-profit, Not-for-profit institutions.
*Estimated Number of Respondents:* 48,430.
*Estimated Burden Hours Per Response:* 4 seconds.
*Frequency of Response:* On occasion.
*Estimated Total Reporting Burden:* 83,192 hours.

*Clearance Officer:* Vicki S. Thorpe (304) 480–6553, Bureau of the Public Debt, 200 Third Street, Parkersburg, West VA 26106–1328.
*OMB Reviewer:* Alexander T. Hunt (202) 395–7860, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

**Lois K. Holland,**
*Departmental Reports, Management Officer.*
[FR Doc. 97–28516 Filed 10–27–97; 8:45 am]
BILLING CODE 4810–40–P

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## DEPARTMENT OF THE TREASURY

### Submission for OMB Review; Comment Request

October 21, 1997.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

*Special Request:* In order to conduct the survey described below in November 1997 timeframe, the Department of the Treasury is requesting that the Office of Management and Budget (OMB) review and approve this information collection by November 3, 1997. To obtain a copy of this study, please contact the Internal Revenue Service Clearance Officer at the address listed below.

**Internal Revenue Service (IRS)**

*OMB Number:* 1545–1432.
*Project Number:* M:SP:V 97–022-G.
*Type of Review:* Revision.
*Title:* 1997 Telephone Routing Interactive System (TRIS) View Debit Application Customer Satisfaction Survey.
*Description:* The purpose of the survey is to assess the level of ease and satisfaction with using the View Debit application.
*Respondents:* Individuals or households.
*Estimated Number of Respondents:* 1,260.
*Estimated Burden Hours Per Response:* 1 minute.
*Frequency of Response:* Other (one time only).
*Estimated Total Reporting Burden:* 21 hours.

*Clearance Officer:* Garrick Shear (202) 622–3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, N.W., Washington, DC 20224.
*OMB Reviewer:* Alexander T. Hunt (202) 395–7860, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

**Lois K. Holland,**
*Departmental Reports Management Officer.*
[FR Doc. 97–28517 Filed 10–27–97; 8:45 am]
BILLING CODE 4830–01–P

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## DEPARTMENT OF THE TREASURY

### Submission for OMB Review; Comment Request

October 21, 1997.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

*Special Request:* In order to conduct the survey described below in November 1997 timeframe, the Department of the Treasury is requesting that the Office of Management and Budget (OMB) review and approve this information collection by November 3, 1997. To obtain a copy of this study, please contact the Internal Revenue Service Clearance Officer at the address listed below.

**Internal Revenue Service (IRS)**

*OMB Number:* 1545–1432.
*Project Number:* M:SP:V 97–023–G.
*Type of Review:* Revision.
*Title:* 1997 Telephone Routing Interactive System (TRIS) Refund Trace Application Customer Satisfaction Survey.
*Description:* The purpose of the survey is to assess the level of ease and satisfaction with using the Refund Trace application.
*Respondents:* Individuals or households.
*Estimated Number of Respondents:* 882.

*Estimated Burden Hours Per Response:* 1 minute.

*Frequency of Response:* Other (one time only).

*Estimated Total Reporting Burden:* 15 hours.

*Clearance Officer:* Garrick Shear (202) 622–3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, N.W., Washington, DC 20224.

*OMB Reviewer:* Alexander T. Hunt (202) 395–7860, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

**Lois K. Holland,**

*Departmental Reports Management Officer.*

[FR Doc. 97–28518 Filed 10–27–97; 8:45 am]

BILLING CODE 4830–01–P

## DEPARTMENT OF THE TREASURY

### Submission for OMB Review; Comment Request

October 21, 1997.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

*Special Request:* In order to conduct the survey described below in November 1997 timeframe, the Department of the Treasury is requesting that the Office of Management and Budget (OMB) review and approve this information collection by November 3, 1997. To obtain a copy of this study, please contact the Internal Revenue Service Clearance Officer at the address listed below.

**Internal Revenue Service (IRS)**

*OMB Number:* 1545–1432.

*Project Number:* M:SP:V 97–024–G.

*Type of Review:* Revision.

*Title:* 1997 Telephone Routing Interactive System (TRIS) View Credit Application Customer Satisfaction Survey.

*Description:* The purpose of the survey is to assess the level of ease and satisfaction with using the View Credit application.

*Respondents:* Individuals or households.

*Estimated Number of Respondents:* 1,260.

*Estimated Burden Hours Per Response:* 1 minute.

*Frequency of Response:* Other (one time only).

*Estimated Total Reporting Burden:* 21 hours.

*Clearance Officer:* Garrick Shear (202) 622–3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, N.W., Washington, DC 20224.

*OMB Reviewer:* Alexander T. Hunt (202) 395–7860, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

**Lois K. Holland,**

*Departmental Reports Management Officer.*

[FR Doc. 97–28519 Filed 10–27–97; 8:45 am]

BILLING CODE 4830–01–P

## DEPARTMENT OF THE TREASURY

### Submission for OMB Review; Comment Request

October 21, 1997.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

*Special Request:* In order to conduct the survey described below in November 1997 timeframe, the Department of the Treasury is requesting that the Office of Management and Budget (OMB) review and approve this information collection by November 3, 1997. To obtain a copy of this study, please contact the Internal Revenue Service Clearance Officer at the address listed below.

**Internal Revenue Service (IRS)**

*OMB Number:* 1545–1432.

*Project Number:* M:SP:V 97–024–G.

*Type of Review:* Revision.

*Title:* 1997 Telephone Routing Interactive System (TRIS) Refund Release Application Customer Satisfaction Survey.

*Description:* The purpose of the survey is to assess the level of ease and satisfaction with using the Refund Release application.

*Respondents:* Individuals or households.

*Estimated Number of Respondents:* 1,260.

*Estimated Burden Hours Per Response:* 1 minute.

*Frequency of Response:* Other (one time only).

*Estimated Total Reporting Burden:* 21 hours.

*Clearance Officer:* Garrick Shear (202) 622–3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, N.W., Washington, DC 20224.

*OMB Reviewer:* Alexander T. Hunt (202) 395–7860, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

**Lois K. Holland,**

*Departmental Reports Management Officer.*

[FR Doc. 97–28520 Filed 10–27–97; 8:45 am]

BILLING CODE 4830–01–P

## DEPARTMENT OF THE TREASURY

### Submission for OMB Review; Comment Request

October 21, 1997.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

*Special Request:* In order to conduct the survey described below in November 1997 timeframe, the Department of the Treasury is requesting that the Office of Management and Budget (OMB) review and approve this information collection by November 3, 1997. To obtain a copy of this study, please contact the Internal Revenue Service Clearance Officer at the address listed below.

**Internal Revenue Service (IRS)**

*OMB Number:* 1545–1432.

*Project Number:* M:SP:V 97–026–G.

*Type of Review:* Revision.

*Title:* 1998 TeleFile Automated Customer Satisfaction Survey.

*Description:* The purpose of the survey is to assess the level of ease and satisfaction with using the TeleFile program.

*Respondents:* Individuals or households.

*Estimated Number of Respondents:* 4,675.

*Estimated Burden Hours Per Response:* 1 minute.

*Frequency of Response:* Other (one time only).

*Estimated Total Reporting Burden:* 156 hours.

*Clearance Officer:* Garrick Shear (202) 622–3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, N.W., Washington, DC 20224.

*OMB Reviewer:* Alexander T. Hunt (202) 395–7860, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

**Lois K. Holland,**

*Departmental Reports Management Officer.*

[FR Doc. 97–28521 Filed 10–27–97; 8:45 am]

BILLING CODE 4830–01–P

## DEPARTMENT OF THE TREASURY

### Submission to OMB for Review; Comment Request

October 21, 1997.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

### Internal Revenue Service (IRS)

*OMB Number:* 1545–0794.

*Regulation Project Number:* LR–311–81 Final (TD 7925).

*Type of Review:* Extension.

*Title:* Penalties for Underpayment of Deposits and Overstated Deposit Claims, and Time for Filing Information Returns of Owners, Officers and Directors of Foreign Corporations.

*Description:* Section 6046 requires information returns with respect to certain foreign corporations and the regulations provide the date by which these returns must be filed. Section 6656 provides penalties with respect to failure to properly satisfy tax deposit obligations and the regulations provide the method for applying relief from these penalties.

*Respondents:* Individuals or households, Business or other for-profit.

*Estimated Number of Respondents:* 60,000.

*Estimated Burden Hours Per Respondent:* 30 minutes.

*Frequency of Response:* On occasion.

*Estimated Total Reporting Burden:* 30,000 hours.

*OMB Number:* 1545–1093.

*Regulation Project Number:* IA–56–87 and IA–53–87 Final.

*Type of Review:* Extension.

*Title:* Minimum Tax—Tax Benefit Rule.

*Description:* Section 58(h) of the 1954 Internal Revenue Code provides that the secretary shall provide for adjusting tax preference items where such items provided no tax benefit for any taxable year. This regulation provides guidance for situations where tax preference items provided no tax benefit because of available credits and describes how to claim a credit or refund of minimum tax paid on such preferences.

*Respondents:* Business or other for-profit.

*Estimated Number of Respondents:* 200.

*Estimated Burden Hours Per Respondent:* 12 minutes.

*Frequency of Response:* Other (one-time claim for credit or refund).

*Estimated Total Reporting Burden:* 40 hours.

*Clearance Officer:* Garrick Shear (202) 622–3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, NW, Washington, DC 20224.

*OMB Reviewer:* Alexander T. Hunt (202) 395–7860, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

**Lois K. Holland,**

*Departmental Reports Management Officer.*

[FR Doc. 97–28522 Filed 10–27–97; 8:45 am]

BILLING CODE 4830–01–P

## DEPARTMENT OF THE TREASURY

**[Treasury Order Number 111–02]**

### Temporary Arrangements for Functions Relating to Tax Policy, Authority Delegation

October 22, 1997.

Pursuant to the authority vested in the Secretary of the Treasury, including the authority vested by 31 U.S.C. 321(b), and notwithstanding Treasury Order (TO) 101–05, it is ordered that the following arrangements shall be temporarily in effect with respect to tax policy functions.

1. The Senior Advisor for Policy, in the Office of Tax Policy, shall report through the Deputy Secretary to the Secretary, and shall be authorized to use the title of, and sign all correspondence as, Acting Assistant Secretary (Tax Policy).

2. All duties and powers of the Assistant Secretary (Tax Policy), including all powers and duties described in TO 111–01, dated March 16, 1981, shall be carried out by the Acting Assistant Secretary (Tax Policy).

3. The Deputy Assistant Secretary (Tax Policy), the Deputy Assistant Secretary (Tax Analysis), and the Deputy Assistant Secretary (International Tax Affairs) shall report to the Acting Assistant Secretary (Tax Policy).

4. *Redelegation.* The duties and powers assigned by this Order may be redelegated. Any such redelegation shall be in writing.

5. *Effective Date.* The foregoing arrangements shall be effective immediately. To the extent that any action heretofore taken consistent with this Order may require ratification, it is hereby approved and ratified.

6. *Cancellation.* TO 111–02, ''Temporary Arrangements for Functions Relating to Tax Policy,'' dated June 12, 1996, is superseded. This temporary Order shall terminate without any further action when a new Assistant Secretary (Tax Policy) executes the oath of office.

**Robert E. Rubin,**

*Secretary of the Treasury.*

[FR Doc. 97–28513 Filed 10–27–97; 8:45 am]

BILLING CODE 4810–25–P

## DEPARTMENT OF THE TREASURY

### Customs Service

### Fee for Customs Services at User Fee Airports

**AGENCY:** U.S. Customs Service, Department of the Treasury.

**ACTION:** General notice.

**SUMMARY:** This document advises the public of an increase in the fee charged for Customs services that are made available at user fee airports pursuant to 19 U.S.C. 58b. The fee reflects the annual cost of providing one Customs inspector at a user fee airport on a full-time basis. The increase in the annual fee is necessary to cover all costs currently incurred by Customs in providing inspectional services at user fee airports, as mandated by the statute.

**EFFECTIVE DATE:** The new fee is effective October 1, 1997, and will be reflected in quarterly user fee airport billings issued on or after that date.

**FOR FURTHER INFORMATION CONTACT:** Gerald Ross, Office of Finance (202–927–0123).

**SUPPLEMENTARY INFORMATION:**

## Background

Section 236 of the Trade and Tariff Act of 1984 (Public Law 98–573, 98 Stat. 2992), as amended (codified at 19 U.S.C. 58b), authorizes the Secretary of the Treasury to make Customs services available and charge a fee for the use of such services at certain specified airports and at any other airport, seaport, or other facility designated by the Secretary pursuant to criteria set forth in the statute. The statute further provides that the fee charged thereunder shall be in an amount equal to the expenses incurred by the Secretary in providing the Customs services at the airport, seaport, or other facility, including the salary and expenses of individuals employed by the Secretary to provide the Customs services.

The Commissioner of Customs has designated a number of airports within the United States as ''user fee airports'' pursuant to the authority set forth in 19 U.S.C. 58b which has been delegated by the Secretary of the Treasury to the Commissioner. Section 122.15 of the Customs Regulations (19 CFR 122.15) concerns user fee airports and includes a list of designated user fee airports. Although there are no other provisions within the Customs Regulations that deal specifically with user fee airports, each Memorandum of Agreement between the concerned airport authority and Customs, under which each user fee airport is established, sets forth the responsibilities of both Customs and the airport which include an agreement by airport to pay a flat annual fee (established at $74,905 for Fiscal Year 1997 which ended on September 30, 1997) to cover the salary and benefits costs of one full-time inspector, plus any related costs for travel, transportation, per diem and cost-of-living allowances, and an agreement by Customs to provide 8 hours of service per day, Monday through Friday, for a total of 40 hours. Each Memorandum of Agreement further provides for an increase in the annual fee as may be necessary to reflect any increase in the costs to Customs for providing the services, as required by the statute.

## Adjustment of Annual User Fee Airport Fee

Based on a review of the annual fee charged in Fiscal Year 1997 with reference to the actual salaries and expenses for Customs personnel assigned to user fee airports as of April 30, 1997, Customs has determined that the annual fee should be increased to $78,500 in order to reflect the true costs to Customs in providing Customs services at user fee airports. The new annual fee is effective October 1, 1997, and will be reflected in quarterly user fee airport billings issued on or after that date.

Dated: October 22, 1997.

**Vincette L. Goerl,**

*Assistant Commissioner, Office of Finance.*

[FR Doc. 97–28489 Filed 10–27–97; 8:45 am]

BILLING CODE 4820–02–P

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# DEPARTMENT OF THE TREASURY

## Customs Service

## Live Entry Requirement for Non-Automated Entry; Comment Request

**AGENCY:** U.S. Customs, Department of the Treasury.

**ACTION:** Notice of meeting and request for comment.

**SUMMARY:** In its efforts to redesign the trade compliance process, Customs would like to develop a more efficient way to process non-automated entry and entry summary documents. This notice announces that a public meeting will be in Hearing Room B of the Interstate Commerce Commission Building in Washington, D.C., commencing at 9:30 a.m. on Friday, November 14, 1997. The purpose of this meeting is to (1) discuss a possible change in regulations to require all non-automated entry documents to be filed as entry/entry summaries before the release of merchandise; (2) discuss differing public interpretations of this issue and (3) explore options for clarifying the differing interpretations. Due to limitations on available seating, those planning to attend are requested to notify Customs in advance. Written comments will also be accepted at the hearing and by mail.

**DATES:** Meeting will take place on November 14, 1997, from 9:30 a.m. to 11:30 p.m. Written comments should be received on or before November 30, 1997, to be assured of consideration in the development of any proposed amendment to the current regulations.

**ADDRESSES:** Meeting will be held in Hearing Room B of the Interstate Commerce Commission Building at 12th Street and Constitution Avenue, NW, Washington, D.C. Written comments regarding this notice should be addressed to Ms. Brenda Brockman, U.S. Customs Service, Room B–102, 1301 Constitution Avenue, Washington, DC 20229.

**FOR FURTHER INFORMATION CONTACT:**

To attend the hearing, please notify Ms. Tonda Moton at (202) 927–1676.

For operational or policy issues: Ms. Kathryn Dapkins at (202) 927–0333.

For regulatory issues: Ms. Gina Grier at (202) 927–2397.

**SUPPLEMENTARY INFORMATION:** In accordance with the Customs Modernization provisions (the Mod Act) of the North American Free Trade Agreement Implementation Act, which gives Customs the flexibility to tailor its commercial operations to meet its needs and capabilities, Customs has undertaken an effort to redesign the entry process. While the majority of all entry summaries are sent to Customs electronically via the Automated Broker Interface (ABI), the remaining summaries are still submitted as non-automated documents. Customs is currently reconsidering the processing of non-ABI, fully paper entry documents.

Importers currently have the option of filing formal, non-ABI entries by one of the following two methods: (1) The entry (CF 3461) is submitted to Customs to obtain release of the merchandise, and the entry summary (CF 7501) along with payment of duties, fees, and taxes, is submitted within ten business days of the date of the entry (date of release of the merchandise); or (2) the entry/entry summary (generally referred to as a ''live'' entry), along with payment of duties, fees, and taxes, is submitted to Customs to obtain the combined effect of processing the documents and paying the duties and then obtaining release of the merchandise.

When a non-ABI entry is filed, Customs manually enters data from the entry documents into its automated system. When the entry summary is submitted, Customs again enters data manually, this time from the summary, into its automated system. This process of handling the entry documents twice is inefficient and burdensome. It also hinders Customs ability to perform the enforcement activities which are a part of its mission.

Customs would like to streamline this process by requiring importers who file non-automated entry documents to file them as entry/entry summaries, along with all documentation and estimated duties, fees, and taxes, prior to the release of the merchandise. This type of ''live entry'' would require only one-time processing by Customs, thereby decreasing the amount of time spent on these non-automated documents and freeing up resources for other work. This one-time processing would allow Customs to more efficiently handle the increase in importations within current resource levels. For importers who file non-automated entry documents, the

two-step process of submitting the CF 3461 to obtain release of goods, and then, within ten business days, submitting the CF 7501 entry summary with payment of duties, fees, and taxes, would be eliminated.

Customs ability to enforce trade laws would also be enhanced if the entry/entry summary were submitted prior to the release of the merchandise. The information on entry summaries tends to be more complete and accurate than that on entries. Having better data up front would make it easier for Customs to pinpoint compliance problems, ensure admissibility, and verify bond sufficiency, as these types of checks are performed manually with non-automated entries.

Customs will hold a public meeting to discuss a possible change in regulations to require all non-automated entry documents to be filed as entry/entry summaries before the release of merchandise. This meeting will begin with a brief description of possible proposals, followed by time for the trade community to ask questions and provide comments. Those wishing to provide verbal comments should so indicate when making seating reservations, and should also submit their comments in writing. Because seating is limited, reservations will be required. Individuals planning to attend are requested to notify Ms. Tonda Moton by fax at (202) 927–1363 or by phone at (202) 927–1676. Written comments will be considered in the development of any proposed amendment to the current regulations, but will not be responded to individually.

Dated: October 21, 1997.

**Charles W. Winwood,**

*Assistant Commissioner, Office of Strategic Trade.*

[FR Doc. 97–28491 Filed 10–27–97; 8:45 am]

BILLING CODE 4820–02–P

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## DEPARTMENT OF THE TREASURY

### Fiscal Service

### Treasury Current Value of Funds Rate

**AGENCY:** Financial Management Service, Fiscal Service, Treasury.

**ACTION:** Notice of rate for use in Federal debt collection and discount evaluation.

**SUMMARY:** Pursuant to section 11 of the Debt Collection Act of 1982 (31 U.S.C. 3717), the Secretary of the Treasury is responsible for computing and publishing the percentage rate to be used in assessing interest charges for outstanding debts on claims owed the Government. Treasury's Cash Management Regulations (I TFM 6–8000) also prescribe use of this rate by agencies as a comparison point in evaluating the cost-effectiveness of a cash discount. Notice is hereby given that the applicable rate is 5 percent for calendar year 1998.

**DATES:** The rate will be in effect for the period beginning on January 1, 1998 and ending on December 31, 1998.

**FOR FURTHER INFORMATION CONTACT:** Inquiries should be directed to the Program Compliance & Evaluation Division, Financial Management Service, Department of the Treasury, 401 14th Street, SW., Washington, DC 20227 (Telephone: (202) 874–6630).

**SUPPLEMENTARY INFORMATION:** The rate reflects the current value of funds to the Treasury for use in connection with Federal Cash Management Systems and is based on investment rates set for purposes of Pub. L. 95–147, 91 Stat. 1227. Computed each year by averaging investment rates for the 12-month period ending every September 30 for applicability effective January 1, the rate is subject to quarterly revisions if the annual average, on the moving basis, changes by 2 per centum. The rate in effect for calendar year 1998 reflects the average investment rates for the 12-month period ended September 30, 1997.

Dated: October 23, 1997.

**Larry D. Stout,**

*Assistant Commissioner Federal Finance.*

[FR Doc. 97–28533 Filed 10–27–97; 8:45 am]

BILLING CODE 4810–35–M

# Corrections

Federal Register
Vol. 62, No. 208
Tuesday, October 28, 1997

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 648

**[Docket No. 971015246-7246-01; I.D. 100897D]**

**RIN 0648-AK44**

### Fisheries of the Northeastern United States; Summer Flounder, Scup, and Black Sea Bass Fisheries

*Correction*

In proposed rule document 97–27821, beginning on page 54427, in the issue of Monday, October 20, 1997, make the following corrections:

1. On page 54429, in Table 1., in the third column, ''1998 quota (percent)'' should read ''1998 quota (pounds)''.

1. On the same page, in Table 2., in the fourth column, ''2Discards²'' should read ''Discards²''.

BILLING CODE 1505-01-D

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. 96-47]**

### City Drug Company: Revocation of Registration

*Correction*

In notice document 97–27144, beginning on page 53338, in the issue of Tuesday, October 14, 1997, make the following correction:

On page 53343, in the first column, in the first complete paragraph, in the 18th line from the bottom, ''$80,000'' should read ''80,000''.

BILLING CODE 1505-01-D

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 1

**[TD 8734]**

**RIN 1545-AU43; 1545-AT77**

### General Revision of Regulations Relating to Withholding of Tax on Certain U.S. Source Income Paid to Foreign Persons and Related Collection, Refunds, and Credits; Revision of Information Reporting and Backup Withholding Regulations; and Removal of Regulations Under Part 35a and of Certain Regulations Under Income Tax Treaties

*Correction*

In rule document 97–25998, beginning on page 53387, in the issue of Tuesday, October 14, 1997, make the following correction:

**§ 1.165-12 [Corrected]**

On page 53416, in the first column, in § 1.165-12, in amendatory instruction 5., in the first and second lines, insert quotation marks around paragraph designations ''(c)(1)(ii) and (iv)'' and ''(c)(1)(ii) and (iii)''.

BILLING CODE 1505-01-D

federal register

Tuesday
October 28, 1997

# Part II

# Department of Health and Human Services

## Food and Drug Administration

## 21 CFR Parts 16 and 900
## Quality Mammography Standards; Final Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 16 and 900**

**[Docket No. 95N–0192]**
**RIN 0910-AA24**

## Quality Mammography Standards

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations governing mammography. Amendments are being made to the requirements for accreditation bodies; procedures for facility certification; and quality standards for mammography personnel, equipment and practices, including quality assurance. This action is being taken to provide increased assurance of adequate and consistent evaluation of mammography facilities on a nationwide level and compliance of the facilities with quality standards. It also carries out the intent of Congress that FDA replace the existing interim rules with more comprehensive final regulations.

**DATES:** This regulation is effective April 28, 1999; except §§ 900.12(b)(8), 900.12(e)(4)(iii), 900.12(e)(5)(i), 900.12(e)(5)(iii), and 900.12(e)(5)(x), which become effective October 28, 2002.

**FOR FURTHER INFORMATION CONTACT:** Roger Burkhart, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20850, 301–594–3332, FAX 301–594–3306.

**SUPPLEMENTARY INFORMATION:**

## I. Background

The Mammography Quality Standards Act (the MQSA) (Pub. L. 102–539) was passed on October 27, 1992, to establish national quality standards for mammography. The MQSA required that, to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, shall be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to FDA.

The MQSA was enacted in response to the growing incidence of breast cancer and its associated mortality rate. Breast cancer is now the most common nonskin cancer and is the second leading cause of cancer deaths among women, after lung cancer. Early detection of breast cancer, typically involving breast physical examination and mammography, is the best means of preventing deaths that can result if the diagnosis is delayed until the onset of more advanced symptoms. Mammograms can reveal breast cancer up to 2 years before a woman or her doctor can feel a lump. In addition, over 90 percent of these early stage cancers can be cured (Ref. 1).

However, according to the General Accounting Office (GAO), a mammogram is among the most difficult radiographic images to read. It must be of high quality for the image to be interpreted correctly. If the image quality is poor, the interpreter may miss an incipient cancerous lesion. This false negative diagnosis could delay early treatment and result in an avoidable death or increased morbidity. It is equally true that poor quality images or faulty interpretations can lead to a false positive diagnosis when normal tissue is misread as abnormal. This can lead to needless anxiety for the patient, costly additional testing, and painful biopsies.

The Senate Committee on Labor and Human Resources held hearings on breast cancer in 1992 and found a wide range of problems with mammography practice in the United States including: (1) Poor quality equipment, (2) a lack of quality assurance procedures, (3) poorly trained radiologic technologists and interpreting physicians, and (4) a lack of facility inspections or consistent governmental oversight.

### *A. Provisions of the MQSA*

The MQSA was enacted to address these deficiencies in mammography practice. Under the MQSA, Congress established a comprehensive statutory scheme for the certification and inspection of mammography facilities to ensure that only those facilities that comply with minimum Federal standards for safe, high-quality mammography services would lawfully continue to operate after October 1, 1994. Operation after that date would be contingent on receipt of an FDA certificate attesting that the facility meets the mammography quality standards issued under section 354(f) of the Public Health Services Act (the PHS Act) (42 U.S.C. 263b(f)).

Specifically, the MQSA required the following:

(1) Accreditation of mammography facilities by private, nonprofit organizations or State agencies that have been approved by FDA as meeting the standards established by FDA for accreditation bodies and that continue to pass annual FDA reviews of their activities. The MQSA also requires that, as part of the overall accreditation process, actual clinical mammograms from each facility be evaluated for quality by the accreditation body.

(2) An annual mammography facility physics survey, consultation, and evaluation performed by a qualified medical physicist.

(3) Annual inspection of mammography facilities, to be performed by FDA-certified Federal or State inspectors. If State inspectors are used, the MQSA requires a Federal audit of the State inspection program by direct Federal inspections of a sample of State-inspected facilities.

(4) Establishment of initial and continuing qualification standards for interpreting physicians, radiologic technologists, medical physicists, and mammography facility inspectors.

(5) Specification of boards or organizations eligible to certify the adequacy of training and experience of mammography personnel.

(6) Establishment of quality standards for mammography equipment and practices, including quality assurance and quality control (QC) programs.

(7) Standards governing recordkeeping for patient files and requirements for mammography reporting and patient notification by physicians.

(8) Establishment by the Secretary of a National Mammography Quality Assurance Advisory Committee (NMQAAC). Among other things, NMQAAC is required to advise FDA on appropriate quality standards for mammography facilities and accreditation bodies.

The MQSA replaced a patchwork of Federal, State, and private standards. Its purpose is to guarantee sufficient oversight of mammography facilities to ensure that all women nationwide receive adequate quality mammography services.

### *B. Interim Regulations*

On December 14, 1993, the President signed legislation (H. Rept. 2202) granting authority to the Secretary (and by delegation, to FDA) to issue temporary interim regulations setting forth standards for approving accreditation bodies and establishing quality standards for mammography facilities. This authorization was provided in recognition of the fact that FDA certification of the approximately 10,000 mammography facilities in the United States could not be accomplished by the October 1, 1994, statutory deadline without streamlining

the rulemaking process for issuing initial standards. Because of the urgent public health need for national mammography standards, Congress decided to grant this interim rule authority rather than extend the deadline to develop standards.

In the **Federal Register** of December 21, 1993 (58 FR 67558 and 58 FR 67565), FDA issued interim rules establishing requirements for entities applying to serve as accreditation bodies and for facilities applying to obtain FDA certification in order to continue the legal provision of mammography services after October 1, 1994. These interim rules became effective on February 22, 1994. They were amended by another interim rule published in the **Federal Register** on September 30, 1994 (59 FR 49808).

*C. Accreditation and Certification*

Operating under the interim regulations, FDA approved the American College of Radiology (the ACR) and the State of Iowa as accreditation bodies and issued certificates to more than 5,000 facilities accredited by these 2 bodies before the October 1, 1994, statutory deadline. Over 4,500 of the remaining facilities were actively involved in becoming accredited on that date. In the fall of 1994, FDA also approved the States of Arkansas and California as accreditation bodies.

In recognition of the fact that a large number of facilities were working to meet accreditation standards at the same time, and cognizant of the extremely heavy demands this placed upon the accreditation bodies, FDA used authority provided by the MQSA to issue 6-month provisional certificates on October 1, 1994, to facilities whose applications for accreditation were sufficiently complete for review and which, on preliminary examination, appeared reasonably likely to receive accreditation. This avoided the major reduction in access to mammography that would have resulted had several thousand facilities been forced to close their doors until the accreditation and certification process could be completed.

By March 31, 1995, the expiration date for the 6-month provisional certificates issued on October 1, 1994, over 8,200 facilities had become fully accredited and certified. Most of the facilities whose accreditation was still in progress satisfied the criteria for the 1-time 90-day extension of the provisional certificate provided by the MQSA and were granted such extensions.

By June 30, 1995, approximately 9,400 facilities had become fully accredited and certified. Several hundred more, primarily facilities that had begun operation after October 1, 1994, or facilities that had previously failed accreditation and were seeking approval after having taken corrective actions, were operating under provisional certificates or 90-day extensions of these certificates. FDA estimates that approximately 800 facilities closed between October 1993 and June 1995. The closings were due to a number of reasons, including failure to apply for certification, voluntary closure, and failure to meet the standards for accreditation, and other reasons unrelated to the MQSA, such as retirement.

*D. Onsite Inspection of Facilities*

At the same time FDA was working with the four accreditation bodies to accredit and certify facilities, the agency was also meeting the MQSA requirement to establish an annual onsite inspection program to monitor facility compliance with the MQSA standards. The bulk of these inspections are performed by State inspectors operating under the contracts that FDA has with 49 States, Puerto Rico, the District of Columbia, and New York City. Federal inspectors inspect Federal facilities and facilities in the remaining States and do audits of the State inspections. FDA has trained and certified approximately 250 Federal and State inspectors for this program. All facilities that completed the certification process had received their first inspections by September 1996 and approximately 70 percent had received their second inspections by the end of March 1997. FDA was pleased to find widespread compliance with the quality standards during these inspections. Only 2 percent of the facilities had one or more of the most serious findings (referred to by FDA as Level 1 findings) during the first round of inspections and that proportion has dropped to less than 1 percent of the facilities inspected so far in the second round.

*E. Development of Proposed Regulations*

In granting interim rule authority to FDA, Congress made clear its intention that the agency replace the interim regulations with more comprehensive regulations as soon as possible. These more extensive regulations were to be developed using the normal ''notice and comment'' rulemaking process and consultation with the NMQAAC.

Apart from the strong congressional encouragement, there were also other reasons why it was important to replace the existing interim regulations for quality mammography with more comprehensive final regulations. The interim regulations were based primarily on the voluntary standards of the ACR's Mammography Accreditation Program (MAP). Utilization of the MAP standards aided greatly in meeting the October 1, 1994, deadline for accreditation and certification of facilities. The application of these standards to all facilities, instead of just those that had sought voluntary accreditation from the ACR, had a significant impact on mammography nationwide. However, the MAP provisions did not cover all areas that required standards under the MQSA, such as mammography of patients with breast implants and experience requirements for some personnel of mammography facilities. Furthermore, in many situations where MAP voluntary standards were relevant, their wording needed to be changed and clarified for use as part of a regulatory program.

One especially significant gap was in the equipment area where the standards under the interim regulations were minimal. To provide greater assurances of quality equipment performance, the ACR, with the Centers for Disease Control and Prevention (CDC), had previously convened expert committees to develop specifications for mammography equipment. The reports of these expert committees were an important basis for the equipment provisions of the proposed regulations.

In addition, the interim standards were required to be issued and implemented prior to FDA developing any significant experience regulating mammography. Because the statute was new and the regulatory scheme it established presented a different and innovative approach, the agency would inevitably develop ideas for improvement in quality and efficiency of implementation as the program developed.

For all of these reasons, it was necessary to replace the interim regulations with more comprehensive final regulations in order to obtain the highest quality mammography that is reasonably achievable. Coincident with the implementation of the interim rules, work was proceeding on the development of final regulations. This effort was aided by the agency's ongoing experience under the interim rules and the advice of members of the NMQAAC. The NMQAAC membership includes health professionals whose work focuses significantly on mammography and representatives of consumer groups. NMQAAC was chartered on July 7,

1993. Nominations for members were accepted until September 7, 1993. The first meeting of the NMQAAC was held February 17 through 18, 1994. At that meeting, and in subsequent meetings in April, July, and September 1994, the NMQAAC reviewed and commented on drafts of portions of the proposed regulations developed by FDA. At its January 1995 meeting, the NMQAAC reviewed the entire body of draft proposed regulations. Many of the requirements in the proposed regulations were based on advice obtained from the members of NMQAAC during these meetings.

Another valuable resource utilized by FDA in the development of the proposed regulations was the guideline entitled, *Quality Determinants of Mammography* (Ref. 2). This guideline was developed by the Quality Determinants of Mammography Panel, with support from the Agency for Health Care Policy and Research (AHCPR), to help eliminate low quality mammography and, thereby, eliminate the adverse consequences it causes. The Panel consisted of a diverse group representing many medical specialties and consumer representatives knowledgeable about mammography.

Proposed regulations were published in the **Federal Register** of April 3, 1996 (61 FR 14856). To facilitate review by the public, they were published in 5 separate documents, as described in the introduction to section III of this document.

*F. Development of the Final Regulations*

A 90-day public comment period ending July 3, 1996, was provided for the proposed regulations. During that time, extensive efforts were made to encourage public comments. Approximately 17,000 copies of the proposed regulations were mailed to the organizations and individuals on FDA's MQSA mailing list, including 1 to every certified mammography facility. The availability of the proposal was announced in Mammography Matters, the newsletter of FDA's Division of Mammography Quality and Radiation Programs (DMQRP), and in the newsletters of professional groups. Copies were also distributed by FDA personnel at professional meetings. By the end of the comment period, approximately 1,900 responses, containing approximately 8000 individual comments, had been received from organizations and individuals. NMQAAC also provided additional comments on the proposal during an April 1996 meeting.

Analysis of the many comments began after the end of the comment period. At the October 1996 meeting, FDA consulted the NMQAAC for advice with respect to some of the more controversial issues raised by the comments. During the January 1997 meeting, the Committee reviewed the entire set of regulations in light of the comments received. The public comments and the advice received from the NMQAAC were used to develop a draft of final regulations, which the members of the NMQAAC had an opportunity to review individually in March 1997.

The majority of the final regulations will become effective April 28, 1999. The interim rules will continue to apply until that date. Certain equipment-related regulations, in § 900.12(b) and (e), will become effective October 28, 2002. This delay in the effective date for certain equipment requirements is intended to minimize the costs associated with equipment improvements. The cost savings are achieved by permitting facilities to implement the improvements as they follow their normal equipment replacement schedule instead of requiring an immediate purchase of new equipment or equipment upgrades.

## II. Highlights of the Final Rule

This section highlights the major features of the final regulations, as compared to the interim and the proposed regulations, and their potential for achieving the MQSA goals of establishing nationwide quality standards for mammography, while maintaining a broad patient access to mammography services. A detailed discussion of the public comments and FDA's response to them is provided under section III of this document.

These final regulations fulfill FDA's responsibility under the MQSA to establish national quality standards for mammography services, with extensive input from NMQAAC. These Federal regulations will be implemented under the MQSA framework whereby mammography facilities are accredited once every 3 years by FDA-approved State or private not-for-profit accreditation bodies, and inspected once every year by FDA-trained and certified State (or in some cases Federal) inspectors. The Federal-State-private sector partnership provides the necessary tools to successfully implement these regulations and realize the MQSA's goal of assuring high quality mammography services for every American woman.

Accordingly, these regulations establish rigorous criteria designed to enhance the quality of mammography services in a manner that is reasonably achievable by mammography facilities. The regulations provide facilities with flexibility in needed areas to meet the important public health goals of these standards. Taken as a whole, the regulations are expected to provide substantial consumer benefits in a reasoned and cost-effective manner.

The final regulations consist of two subparts. Subpart A is composed primarily of the requirements to be met by the accreditation bodies who perform the crucial initial screening of mammography facilities for quality, including clinical image review, subpart B establishes quality standards to be met by the mammography facilities and administrative procedures.

*A. Accreditation Body Requirements*

The final regulations refine and codify policies FDA had developed under the interim regulations for the initial approval of accreditation bodies by FDA, and for defining the ongoing responsibilities of these bodies and the agency's oversight of them. The primary goal of the accreditation body requirements is to ensure that there is nationwide consistency, both within and between accreditation bodies, in the evaluation of mammography units and procedures to determine if they meet the standards for quality mammography.

The major change made from proposed §§ 900.3 through 900.7 was the removal of several provisions that would have assigned compliance responsibilities to the accreditation bodies. Removal of these provisions ensures that the activities of the accreditation bodies will have their proper focus, which is to identify facilities that are not performing adequate quality mammography and to advise such facilities on the nature of their problems and how to correct them. Compliance activities under the MQSA are reserved for FDA.

*B. Facility Quality Standards*

1. Personnel Standards

The personnel standards of § 900.12(a) cover interpreting physicians, radiologic technologists, and medical physicists who provide services to mammography facilities. The goals of the standards are to ensure that personnel: (1) Have general qualifications in radiology; (2) possess specific qualifications in mammography; and (3) keep their qualifications up-to-date.

Most of the proposed changes in the personnel area were intended to clarify general statements in the interim regulations that have caused confusion in interpretation. A major step to improve quality of personnel

performance, however, was the proposed establishment of initial and continuing experience requirements for radiologic technologists and medical physicists. These requirements are parallel to requirements already in the interim regulations for physicians and, like the physician requirements, are intended to make sure that individuals have supervised clinical experience before they begin to provide mammography services independently, and that they maintain their skills through regular performance of their duties. These new experience requirements have been codified in the final rule after some adjustments in the amount of experience required due to practical considerations, such as the difficulties that medical physicists under contract to one facility would face in attempting to meet the proposed requirement to do surveys in several facilities.

Another significant change from the proposed personnel standards is that the final rule ''grand parents'' technologists who met the personnel requirements under the interim regulations. Without grand parenting technologists already in the system, there was the possibility that localized shortages of technologists would occur, resulting in a serious, short-term impact on access to mammography. Because the agency believes that most technologists presently providing mammography services either meet, or have qualifications comparable to the final requirements, grand parenting could be permitted to relieve these concerns without any significant impact on quality.

2. Equipment

The equipment standards in § 900.12(b) are intended to ensure that mammography equipment has the capability of producing quality mammograms over the full range of clinical conditions. The equipment area was addressed only briefly in the interim regulations. To better define the equipment capabilities needed for high quality mammography, equipment specification standards were proposed for all equipment components of the mammography system from the X-ray generator to the view box. These proposals relied heavily upon the recommendations of the equipment focus groups convened in the early part of the decade by the ACR, with the support of CDC.

After reviewing the information provided in the public comments and by the NMQAAC, FDA revisited the question of the proper balance between the economic impact of new standards and the associated gains to the public health. This reconsideration led the agency to conclude that the expected benefits from some of the proposed equipment specifications would not compensate for the cost to replace or retrofit mammography systems to meet them. The agency has concluded that, in some cases, the same public health goals could be accomplished through specified quality assurance procedures. Accordingly, specifications related to source-image receptor distance (SID), focal spot location, filtration, and film processors have been eliminated and specifications related to compression and radiation output are being treated as performance standards under the quality assurance section of the regulations. Similarly, performance outcome aspects of the requirements for alignment have been moved to the quality assurance section. Finally, requirements related to system resolution were eliminated as duplicating performance standards already in the quality assurance section, and the requirements related to the examination of disabled patients were eliminated in part because of a lack of consensus about the need for such requirements.

In an effort to reduce costs, FDA is phasing in the equipment requirements, with some becoming effective the same time (18 months) as the rest of the regulations and others within 5 years. However, based on the desire not to impede technological advances, the uncertainty in estimating needs further in the future, and an assessment of the associated costs, the agency has eliminated the proposed 10-year phase-in requirements and some of the 5-year phase-in requirements. The agency intends to reassess the need for the deleted requirements at a future time.

3. Recordkeeping and Reporting Requirements

The recordkeeping and reporting requirements of § 900.12(c) are intended to: (1) Ensure that all patients and their referring physicians receive timely and adequate notification of the results of examinations, and (2) assist in diagnosis by ensuring that records of past examinations, including the original mammograms, are available when needed for comparison with the images produced during new examinations.

With respect to patient notification of examination results, the final rule codified this essential reporting requirement as a performance outcome standard. The proposed rule would have required the facilities to have a system to ensure that all patients received written notification of their examination results, and further specified what should be included in that notification. The final rule requires that each facility have a system to ensure that the results of each mammographic examination are communicated to the patient in a timely manner. Thus, the focus is placed on the desired performance outcome, the notification of the patient in a timely manner, and not on the method or specific conduit of the notification. Under the final rule, the facility has the flexibility to use the method of notification that is most effective in its situation and to convey the information to the patient that it deems to be most important. In the part of the preamble discussing this provision, FDA continues to endorse the use of written notification as the most reliable way to guarantee that each patient is notified of results and that any necessary followup will occur and recommends that facilities follow the AHCPR guidelines on direct written notification to all patients. The agency also describes other methods that may achieve the desired outcome equally well in specific situations.

With respect to providing patients with original mammograms upon request, the final rule was modified to make it clear that the original mammograms must be made available to other medical facilities, at the patient's request, whether the transfer is permanent or temporary. It is expected that this change will end the difficulties in obtaining previous original mammograms for comparison with new mammograms (an essential aid to diagnosis) that many patients have experienced under the interim regulations.

4. Quality Assurance

The goal of the quality assurance requirements of § 900.12(d), (e), and (f) are to ensure that equipment and personnel continue to perform at adequate levels. Section 900(d) defines staff responsibilities and recordkeeping requirements for the quality assurance program, § 900.12(e) establishes equipment QC requirements, and § 900.12(f) outlines the requirements for mammography medical outcome audits.

The proposed equipment QC requirements represented a major transition towards performance outcome standards. The interim regulations had referenced the ACR quality assurance manuals and thus specified not only the performance outcomes to be achieved but the test procedures to be followed. The proposed rule was intended to establish the desired performance outcomes and the required frequency of testing at levels nearly identical to those in the interim regulations, but sought to give the mammography facilities some

flexibility in the testing procedures to be used.

The final rule leaves the testing frequencies and the performance outcomes largely unchanged from the proposal, with the exception that standards have been added for radiation output, alignment, and compression, parameters previously considered under the equipment specifications. The provisions related to retesting after equipment failure and taking equipment out-of-service until problems are solved have also been modified to give the facility more flexibility in determining when performance is compromised sufficiently to warrant such actions.

5. Medical Outcomes Audit

A comprehensive mammography medical outcomes audit program can ensure that a facility is providing its patients with accurate mammography examinations and followup care and has the potential to provide the basis for performance outcome standards. However, the public comments made it clear that more research is needed before the state-of-the-art will be sufficiently advanced to support regulatory performance outcome requirements based on audits. FDA did move a step beyond the interim requirement that each facility have a system for reviewing outcome data by codifying requirements related to the analysis of the data collected.

6. Consumer Complaint Mechanism

Under the interim regulations, accreditation bodies have developed mechanisms for addressing consumer complaints about the quality of mammography services received. Requirements for such mechanisms have been continued in § 900.4(g) of the final regulations. FDA recognized, however, that consumer complaints usually can be addressed most effectively at the facility level. For this reason, FDA proposed to require each facility to develop a system for collecting and resolving consumer complaints, with special emphasis placed on the resolution of serious complaints. This requirement has been codified with little change in § 900.12(h). The accreditation body and FDA retain the responsibility for addressing complaints that cannot be resolved at the facility level.

7. Alternative Requirements

The alternative requirements in § 900.18 provide a mechanism for implementing advances in mammography that meet quality standards more rapidly than would be possible through amending the regulations. This mechanism will be used only when the potential public health benefits justify such actions.

This section was incorporated into the proposed rule from the interim regulations with little change. Before codification in the final rule, the section was modified to give the agency the authority to allow an approved alternative to be used by entities other than the entity that applied for approval. This change was made in response to concerns that it would be an unnecessary duplication of effort for the agency and for the applicants if multiple applications were required for the approval of the same advance in mammography.

8. Performance Outcomes

FDA's proposed rule invited comments on the possibility of taking a performance outcomes approach to mammography quality standards. Suggestions and comments on possible performance outcome indicators were also invited. As discussed in more detail elsewhere in this document, the consensus of the public comments was that while the performance outcome concept was attractive in theory, much additional research will be needed before a performance outcome system to ensure mammography quality can be issued. The agency agrees with this consensus but also believes that it is possible to start moving in that direction in certain areas as noted in the previous discussion.

## III. Provisions of the Final Rule

The proposed regulations that published in the **Federal Register** of April 3, 1996, consisted of five separate documents. The first, ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches'' (61 FR 14856 (Docket No. 95N–0192)): (1) Surveyed the history of efforts to implement the MQSA; (2) summarized FDA's analysis of the environmental, economic, and paperwork impacts of the final regulations; and (3) set out the agency's proposed ''scope'' and ''definitions'' sections (§§ 900.1 and 900.2). In that document, the agency also invited public comments on the concept of performance-based outcomes regulations and the feasibility of recasting the proposed design and process requirements into performance-based outcomes requirements.

The second, ''Quality Standards and Certification Requirements for Mammography Facilities; General Facility Requirements'' (61 FR 14870 (Docket No. 93N–0351)), proposed regulations covering a variety of areas, including: (1) Applicability (§ 900.10); (2) requirements for certification (§ 900.11); (3) procedures for suspension or revocation of accreditation; (4) accreditation body approval; (5) facility certificates (§§ 900.13 and 900.14); (6) the process for appealing agency decisions (§ 900.15); and (7) an alternative requirement process (§ 900.18). Some aspects of the facility standards were also covered. These included medical records and recordkeeping (§ 900.12(c)); general quality assurance requirements (§ 900.12(d)); mammography medical outcome audits (§ 900.12(f)); mammography of examinees with breast implants (§ 900.12(g)); the consumer complaint process (§ 900.12(h)); and additional clinical image review and patient notification (§ 900.12(I)).

The third, ''Proposed Requirements for Accreditation Bodies of Mammography Facilities'' (61 FR 14884 (Docket No. 95N–0192)), covered the approval, responsibilities, and withdrawal of approval of accreditation bodies (§§ 900.3 to 900.7).

The fourth, ''Quality Standards and Certification Requirements for Mammography Facilities; Personnel Requirements'' (61 FR 14898 (Docket No. 95N–0215)), proposed standards to be met by interpreting physicians (§ 900.12(a)(1)), radiologic technologists (§ 900.12(a)(2)), and medical physicists (§ 900.12(a)(3)) working in mammography facilities.

The fifth, ''Proposed Quality Standards for Mammography Equipment Quality Assurance'' (61 FR 14908 (Docket No. 95N–0195)), proposed equipment specifications (§ 900.12(b)) and requirements for the equipment quality assurance program (§ 900.12(e)).

The proposed regulations were published in these five segments to facilitate review and make it easier for members of the public to focus on the sections of most interest to them. Because the final regulations are being issued as a single document, the comments received in response to the proposed regulations are addressed as part of this single preamble rather than in separate documents relating to each of the five proposal documents. General comments are treated first, followed by a discussion of the public response to the concept of performance outcome requirements and their feasibility. Then comments on the individual components of the final regulations are discussed in the order that each component appears in the final regulations.

Finally, the comments on the FDA's analyses of impact are discussed in sections V of this document, and section VI covers the Paperwork Reduction Act of 1995 provisions. Citations for individual provisions of the regulations

generally have remained the same; the preamble clearly notes any instance in which a provision has been codified under a new citation.

Each of the five proposed regulations was preceded by a preamble containing a wide range of information intended as background and information for the final regulations. Comments that the agency received relating to preamble discussions have been addressed either with the general comments or with the specific regulation sections to which they are most closely related.

*A. General Comments*

Many comments received on the proposed regulations raised issues or concerns that were broader in scope than any specific provision. These more general comments are responded to first, before turning to the more specific comments.

1. The Overall Value of the Quality Standards

(Comment 1). A number of the comments stated opposing positions on the overall value of the quality standards established by these regulations. Seventeen comments supported the quality standards with only minor modifications, noting that they would strengthen radiology practices and enhance the quality of mammography. Twenty-six comments, on the other hand, opposed the quality standards in their entirety. Reasons given included concern about costs and the resultant impact on access, opposition to the regulation of medicine, a characterization of the standards as unnecessary micro-management, belief that more stringent standards were unnecessary or ineffective in improving quality, and an opposition to ''international'' requirements for mammography practice.

The agency recognizes the need to balance the benefits to be achieved from improved quality of mammography with the cost of those improvements and the impact such cost might have on access to mammography. Congress addressed the concern with that balance in drafting the MQSA and has guided the agency in its efforts to implement the statute. An independent evaluation of the program performed by GAO determined that the interim regulations had a positive effect on the quality of mammography without a serious adverse impact on access (Ref. 2). Although, as previously mentioned, a number of facilities did close for various reasons, service from another provider was generally available within 25 miles. Newly established facilities have continued to be certified, further mitigating any impact on access. Based upon its experience with the interim regulations and advice from NMQAAC members, FDA believes that the proposed regulations will achieve further improvements in quality at a cost that will not impact access significantly. The public comments on the proposal led to a further refinement of the regulations, including removal of requirements when the comments persuaded the agency that the requirement was not essential. These changes, and the associated reduction in cost, should provide an even more favorable ratio of benefit to cost.

In answer to concerns about micro-management, many of the specific provisions added in the final regulations reflect practices and policies that were developed under the interim regulations. These policies were developed in response to requests from mammography facilities for information on how to meet the requirements of interim regulations and are already being followed by most facilities. Incorporating these policies into the final regulations gave interested parties the opportunity to comment on them. In response to the comments, requirements have been refined to achieve the most favorable balance between benefit and cost.

Finally, FDA notes that the system for ensuring quality mammography established by the MQSA and these regulations is unique to the United States and is not a duplicate of, or related to any international requirements or systems established in any other country.

(Comment 2). Two comments, while apparently not in total opposition to the regulations, did express their authors' opinions that the personnel and recordkeeping and reporting requirements went ''far beyond FDA's medical device mandate.''

FDA notes that the authors of these comments have overlooked the fact that these regulations are issued under the MQSA, which amended the Public Health Service Act, not under the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (the act). The MQSA specifically requires the agency to develop standards for personnel qualifications and for reporting and recordkeeping (42 U.S.C. 263b(f)).

(Comment 3). Several comments, while expressing varying degrees of support or opposition to the requirements, asked why mammography has been singled out for such attention. Some suggested that other diseases were as serious or more serious than breast cancer, while one comment pointed out that the radiation levels in mammography are quite low.

Although a case might be made for developing similar programs for diagnosis of other diseases, Congress decided that mammography should be the subject of this legislation. Congress found the evidence sufficiently convincing that breast cancer was a significant public health risk that could be reduced by improved mammography and, furthermore, that the performance of mammography nationwide was in need of improvement. Congress responded with the MQSA, and FDA is carrying out the mandate of that statute. FDA agrees with the comment that observed that the radiation levels in mammography are much lower than they were 20 years ago (largely as a result of a cooperative government, industry, and facility effort) and lower than those used in many other examinations. However, the primary concerns addressed by the MQSA are not radiation levels but poor image quality and interpretation.

(Comment 4). One comment criticized the proposed regulations for not sufficiently recognizing local facility condition variations, indicating that standards appropriate for some facilities might be unduly burdensome to others. In contrast, another comment strongly supported the application of uniform standards in both rural and nonrural areas. It stated that this would ensure that women in rural areas received optimum care.

FDA believes that all women are entitled to high quality mammography, no matter where they live, and so has not issued lesser standards for rural areas or any other subset of facilities. The agency further notes that the fear that applying uniform minimum standards would cause an undue burden to rural facilities is refuted by the experience of Michigan, where such uniform standards have been applied to all facilities in that State since 1989 (Ref. 3), and by experience under the Federal interim regulations.

(Comment 5). Ten comments stated that ''the regulations and the complaint process may confuse the public by bringing up more issues than it is necessary for them to be concerned with and confusing the role of mammography in the overall diagnosis and treatment of breast cancer.''

The purpose of the MQSA is to ensure adequate quality mammography for all patients. If this purpose is achieved, members of the public will be able to receive mammography at any facility in the country without having to be concerned about the issues covered by the regulations. Thus, public

''confusion'' should decrease rather than increase as a result of these regulations. Without additional details, FDA cannot respond further to the concern expressed by the comments about confusion over the role of mammography. The agency assumes, however, that any such problems could be handled through educational efforts.

2. Division of Responsibility

The MQSA established a system of checks and balances involving the interaction of several groups, including FDA, the States, and the accreditation bodies. A number of comments expressed varied concerns about the division of responsibility established by the proposal.

(Comment 6). One of these comments stated that oversight and review of mammography facilities is the backbone of the MQSA program. Along with a second comment, it noted that FDA, not the accreditation bodies, should be responsible for enforcement actions.

FDA agrees with this comment and believes that the final regulations clearly give the agency the primary responsibility for this function. However, the regulations also establish that the accreditation bodies have responsibility for notifying FDA when they have information that enforcement actions may be needed and for assisting in related investigations.

(Comment 7). Two comments stated that the regulations should allow States to eliminate overlapping functions if they are serving as both accreditation bodies and inspection agencies. A third comment stated that more leeway should be given to State accreditation bodies, which have enforcement capability, than to non-State accreditation bodies. A fourth comment recommended eliminating some unspecified requirements if a State agency holds both accreditation body status and an inspection contract.

FDA agrees that states that are both accreditation bodies and inspection agencies may be able to combine some functions and, in fact, some steps have been taken under the interim regulations. However, it is important that all facilities meet the same accreditation and inspection requirements. The agency believes it is unlikely that any requirements pertaining to accreditation bodies or facility standards can be eliminated entirely in States with dual status. The need for consistency also explains why FDA disagrees with the third comment; State accreditation bodies may have enforcement capability under State law but this capability could vary greatly from State to State. As the author of the fourth comment did not give specific examples of requirements to be eliminated, the agency cannot respond further to that comment.

(Comment 8). Three comments suggested that to reduce costs there should be one comprehensive system to accomplish all the necessary accreditations within any State that already has in place a mechanism for accreditation of facilities and licensure of technologists. The comment observed that the Federal Government would have to subsidize States for this work.

States are permitted under the MQSA to apply to become FDA-approved accreditation bodies (42 U.S.C. 263b(e)(1)(A)) and three States have already done so. FDA disagrees that the agency should merely substitute existing State accreditation and licensing systems for the MQSA standards. States may have widely different accreditation standards under their State laws, while the drafters of the MQSA envisioned a system that would establish uniform, minimum national standards for all mammography facilities. The MQSA, however, expressly permits State laws relating to mammography that are more stringent to be issued or to remain in effect (42 U.S.C. 263b(m)). Furthermore, the drafters of the MQSA did not provide for Federal subsidies for any accreditation body; the statute instead expects those bodies to be supported by their accreditation fees.

(Comment 9). One comment recommended the adoption of only one set of rules, whether it be established by the State, ACR, or FDA, to govern mammography, while a second recommended combining FDA and ACR into one ''accreditation body'' to reduce the problems of complying with the requirements of both. Another comment objected to FDA permitting States to pass additional laws and regulations governing mammography in addition to the MQSA requirements. It stated that this would prevent the establishment of consistent nationwide standards. Another comment objected to the absence of a preemption clause in the MQSA, fearing that would lead to overlapping State and Federal regulations.

FDA notes that, within the limits of the authority given to it by the MQSA, it has worked towards the goal of one set of rules. The MQSA authorizes FDA to establish one set of uniform baseline standards and to require that all approved accreditation bodies, including ACR, enforce standards substantially the same as these. The agency has taken this step. FDA also notes that the Health Care Financing Administration (HCFA) has agreed to accept the MQSA regulations and inspections in lieu of the regulations and inspection system it had previously established to govern mammography under Medicare, thus reducing duplication. The MQSA also requires State standards to be at least as rigorous as those of FDA. However, as noted by the comment that there is no preemption clause in the statute, the MQSA explicitly gives States authority to develop additional regulations governing mammography, as long as they are more stringent than the MQSA requirements (42 U.S.C. 263b(m)). The intention of the MQSA was to create a uniform nationwide baseline quality level for mammography, while permitting individual States to strive for higher levels. Only Congress can make changes in this approach, not FDA.

(Comment 10). One comment expressed concern that the nature of the State/Federal agency relationship may be an impediment to ensuring quality mammography. The author cited two GAO reports criticizing the oversight of State programs by other Federal agencies. FDA notes that the agency has a long history of Federal-State cooperative programs, especially with respect to educational efforts and inspections in the medical X-ray area, and that, in general, these programs have been very successful. As the agency moves into new areas of cooperation with the States, it is studying the experiences of other Federal agencies in an effort to avoid any difficulties they may have experienced in working with the States.

(Comment 11). One comment recommended that FDA's mammography oversight be limited to equipment standards and requiring that facilities be accredited and that oversight of the accreditation bodies by FDA be reduced. Another comment suggested limiting FDA's oversight only to ensuring that facilities are accredited properly by the accreditation bodies.

FDA notes that the MQSA gives FDA far greater responsibilities than either of these comments would permit and the regulations are intended to help the agency continue to fulfill its obligations under the statute.

(Comment 12). Similarly, two comments made the general recommendation that the accreditation bodies be given expanded responsibilities. Other comments had more specific opinions, for or against, certain expanded responsibilities for the accreditation bodies. Two comments stated that the accreditation body should be the sole evaluator of the annual physicist survey, with the MQSA inspector merely accepting the

accreditation body's review. A third comment argued, however, that valuable information would be lost if the inspector accepted the accreditation body's review of the report and a fourth comment agreed that, if duplicate review is not cost effective, it would be more appropriate for the inspector to review the survey than the accreditation bodies. Three comments stated that the accreditation body should be responsible for tracking all personnel requirements for a facility, while a fourth would give the accreditation body responsibility for review of continuing education credentials. Similarly, a fifth comment would limit the inspections to review of the physicist survey and the QC program, plus taking a phantom image, leaving oversight of the other areas to some unspecified group. Another comment on the appropriate division of responsibilities stated that FDA should not have inspectors performing tests that have already been conducted by medical physicists and technologists.

FDA has utilized, and plans to continue utilizing, the expertise of the accreditation bodies to the maximum extent permitted by the statute. The agency also realizes that the checks and balances system required by the MQSA leads to some duplication of effort between the accreditation body and the inspectors or the inspectors and the medical physicists. However, one of the weaknesses of the pre-MQSA oversight system for mammography was the lack of an onsite evaluation of the facility programs by an individual independent of the facility. Experience with the interim regulations has demonstrated the value of such inspections; the great majority of findings were for situations that had not been identified by the accreditation bodies or the medical physicists. On the other hand, there is no doubt that the accreditation bodies and the medical physicists have prompted the correction of many problems before the inspections took place. These activities and results demonstrate the strength of the program. The agency believes that the drafters of the MQSA were correct in concluding that a checks and balances system, involving two or more entities, would be more effective in ensuring the continued maintenance of high quality mammography than the use of only one entity or the other.

(Comment 13). Two comments recommended that the information obtained by either the accreditation bodies or the inspectors should be shared with the other groups to cut down on unnecessary duplication of information collection activities or submission requirements for the facilities.

FDA agrees with this comment and the statute itself supports elimination of collection of duplicative information (42 U.S.C. 263b(d)). Under the interim regulations, the agency has been working with the accreditation bodies on the electronic exchange of information and will continue to do so under the final regulations.

3. Inspections and Inspectors

A number of the more general comments addressed various aspects of the annual and audit inspections.

(Comment 14). Two comments suggested that the FDA facility inspections should be reduced or eliminated in order to reduce the costs to facilities or because annual inspections are not needed. A third comment urged that inspection frequencies not be included in regulations.

Annual onsite inspections are required by the MQSA (42 U.S.C. 263b(g)); that requirement cannot be changed by the agency, even if it is not in regulations. The agency is evaluating alternative ways for conducting inspections in the hopes of reducing costs for facilities.

(Comment 15). One comment stated that it was inconsistent for FDA to inspect every facility every year while the accreditation bodies are required to visit a much smaller number of facilities annually. The comment further maintained that the MQSA inspections duplicated other inspections.

The FDA inspections and the accreditation body visits serve two different purposes. The MQSA inspections, which are required to be annual, are intended to ensure that all facilities continue to meet the MQSA quality standards. The MQSA requirement that accreditation bodies visit a sample of their facilities each year serves an additional purpose, which is to have accreditation bodies evaluate their own performance and the effectiveness of their accreditation procedures (42 U.S.C. 263b(e)(4)(A)). In addition, accreditation bodies, at FDA's request or on their own authority, will visit facilities that have been identified as potential problem facilities for the purpose of identifying the problems and assisting the facility in correcting them.

(Comment 16). Eleven comments suggested that ACR be designated as the inspection organization in New Mexico.

FDA is unable to consider this suggestion because the MQSA specifically limits inspectors to Federal or State personnel (42 U.S.C. 263b(g)).

(Comment 17). Three comments were concerned about the standards for FDA inspectors and two more urged additional training for inspectors. Another comment was very complimentary of inspectors in Iowa. Fifteen other comments expressed various concerns about the inspection fees.

These issues are beyond the scope of these regulations, which cover requirements for accreditation bodies and quality standards for facilities only. FDA has referred these comments directly to the components of FDA that deal with inspector training and inspection fees.

4. Public Participation in the Process

(Comment 18). Three comments expressed concern that not enough public input has been obtained during the regulation development process and suggested that facilities, manufacturers, and personnel should be interviewed.

The NMQAAC is composed of representatives of the mammography community and consumer groups and has been a valuable conduit of public input during the eight meetings at which it discussed the final regulations before and after they were published. Furthermore, each meeting included an open session during which members of the public could make statements and many individuals took advantage of these opportunities. Finally, there were three public comment periods during the development of the regulations. The first of these was for comments on the interim regulations. A great deal of information was gained for use in the development of the final regulations from comments received at this time. The second was after preliminary drafts of the equipment and medical physicist standards were released and again valuable information was obtained from the public. The third opportunity to comment was after the publication of the proposed regulations and, as previously discussed, approximately 1,900 responses covering every area of the regulations were received from a broad spectrum of organizations and individuals. FDA believes that the public has had ample opportunity to participate in the regulation development and reiterates that this public participation had a significant impact on its final form.

(Comment 19). Another comment recommended prohibiting NMQAAC members from also serving on advisory boards or as consultants to accreditation bodies in order to avoid the possibility that a limited number of people will have disproportionate influence on the program.

In forming the NMQAAC and its other advisory panels, FDA has complied with the Federal Advisory Committee

Act (the FACA), the agency's implementing regulations at 21 CFR part 14, and the MQSA. The FACA requires each advisory committee to be fairly balanced in terms of the points of view represented and the MQSA expressly describes the constituent segments of the affected community that are to have representatives on the Committee (42 U.S.C. 263b(n)). Because advisory committees enlist the expertise of outside consultants to advise the government, it is frequently the case that well-qualified members are nationally recognized experts who are also called upon to play leadership and consultant roles for private groups. The agency does not prohibit such individuals from providing government service if the agency determines that such participation is in the best interest of the government because the need for such participation outweighs the potential conflict of interest. The existence of any potential conflicts are stated for the public record at the beginning of each advisory committee meeting and panel members who have conflicts on particular matters may be prohibited from voting on those issues.

5. Double Reading

In the preamble to the proposed rule (61 FR 14870 at 14876, April 13, 1996), FDA noted that one of the comments received on the interim regulations suggested that all mammograms be read a second time by a second qualified physician. The author of the comment stated that this would avoid unnecessary surgery and emotional stress that can arise from a false positive reading and the lack of appropriate followup in the case of a false negative reading. The agency did not include such a requirement in the final regulations but asked for further comments on the issue.

(Comment 20). Twenty four comments argued against a double reading requirement, basing their opposition on such reasons as the cost, the difficulty of achieving double reading, the delays in reporting to the referring physician leading to patient dissatisfaction, and the belief that it would be a meaningless exercise and only a few abnormalities would be picked up. Comments asserted that the burden would be especially great in rural and isolated areas and could reduce access to mammography services. Twelve of these comments also questioned where the notion of double reading would lead; and would there be a press for triple and quadruple reading. One of these comments urged that the focus be on training for the first reader so that double reading is not necessary. On the other hand, three comments offered strong support for the use of double reading and one comment went so far as to say that all films should be double read in order to eliminate the trauma and psychological stress associated with false positives. One comment suggested requiring double reading for all positive mammograms.

FDA has determined not to include a double reading requirement in the final regulations. Double or multi-reading (as it is now called by the agency for reasons discussed with the comments on § 900.2) is referenced in the regulations only as a way for interpreting physicians at low-workload facilities to meet their continuing experience requirements. Although this practice is not being required, the regulations do not preclude double reading. FDA encourages facilities that believe their services will benefit from such procedures to establish the practice as a quality assurance measure.

6. The Organization of the Final Regulation

(Comment 21). A number of comments were extremely critical of the organization of the proposal, finding it difficult to read and to see the relationship between the five separate divisions, each with its own docket number, preamble, and regulatory content. Several of these comments stated that information on the organization of the proposal should have been provided, while others made suggestions for reorganization of the material when it was published as a final regulation.

FDA adopted the method of presentation in the preamble of the proposals in an effort to make it easier for readers to focus on the provisions that were of most concern to them. Readers interested primarily in the personnel requirements, for example, would need consider only the fourth division, while those whose concerns were primarily equipment-related, could focus on the last division. Although the summary section of each of the five divisions identified the material being provided in the other divisions, it is clear from the comments that further explanation would have been helpful.

The final regulations are being published in a single document. This single document follows the usual **Federal Register** format of a preamble and a regulation section. The regulation section combines the regulations from the five divisions of the proposal in numerical order from §§ 900.1 to 900.18, with some sections reserved for later use. For the convenience of the reader, a table of contents is provided.

7. Other Comments

(Comment 22). Additional comments were received on widely varied topics. One comment noted that mammography services are provided for men and women, and suggested that any mention of ''women'' should be replaced by ''women and men.''

FDA agrees that men are also consumers of mammography services. However, because breast disease and diagnosis overwhelmingly affects women, that word seems more appropriate. However, the agency notes that in the regulations themselves and at many places in the preamble, the term ''patient'' is used. FDA believes this terminology addresses the comment's concern.

(Comment 23). Four comments took issue with statements in the preamble to the proposed regulations concerning the expected benefits from improved mammography and the number of expected deaths from breast cancer.

FDA is aware that several aspects of these issues are unsettled and that authorities may draw different conclusions from the same data. However, the authors of the comments did not appear to challenge the statute's underlying assumption that mammography can be valuable in combating a serious public health threat, even though they might disagree on the quantification of that value.

(Comment 24). Three comments urged FDA to delay the final regulations until a study of the impact of the interim regulations could be conducted to determine what changes were needed or even if the MQSA itself were necessary. Congress intended that final regulations be in place before October 1, 1994, so that the benefits of improved mammography could be realized as soon as possible. Recognizing the magnitude of the task, Congress provided FDA with interim rule authority that would require regulations to be issued in two steps. The first step was the interim regulations, which led to significant benefits. Neither Congress nor the agency believes that any further delay in completing the second stage and achieving the increased benefits of the final regulations can be justified. The agency notes, however, that facilities have been operating under the interim rules for over 2½ years and inspections against the interim regulations have been occurring for over 2 years. This experience with the interim regulations and the problem areas that were identified have contributed significantly to the provisions of the final regulations.

(Comment 25). One comment asked the agency to clarify who makes the decisions about the MQSA regulations.

FDA assumes that the author is referring to decisions about interpretations of the regulations, including decisions about the adequacy of particular training programs for mammography personnel. These decisions are made primarily in FDA's DMQRP (address above).

(Comment 26). Four comments expressed concern that the more unique mammography regulations become, the greater the likelihood that generalists will be forced out of the field.

Many of the personnel requirements, such as licensing and certification, are general requirements of the medical field. In addition, Congress determined, and FDA agrees, that mammography is a sufficiently unique and difficult examination to require specialized training and experience in the production and interpretation of the images and in the testing and maintenance of the equipment. However, it does not require a full-time mammography practice to meet the experience requirements specific to mammography and the specific training requirements are only a fraction of what is required for other purposes, such as completing a residency program or maintaining certification from the American Registry of Radiologic Technologists (ARRT). Thus, individuals will be able to meet the MQSA requirements without limiting their activities to mammography and so there will still be room for generalists.

(Comment 27). A number of comments expressed a variety of concerns about matters outside the scope of these regulations or beyond FDA's authority. These concerns included: (1) Questions about the appropriate frequency for screening mammography and the levels of Medicare reimbursement; (2) a recommendation that a State advisory board be created to monitor each State's mammography program; and (3) a concern about the perceived domination of medicine by big business. Because these comments are beyond the scope of these regulations, these comments will not be addressed.

*B. Alternative Approaches to Quality Mammography*

Executive Order 12866 requires Federal agencies to identify and assess alternative forms of regulation and, where feasible, specify performance objectives (performance or outcome-based standards), rather than specifying the behavior and manner of compliance that regulated entities must adopt (design-specification standards). In addition, Executive Order 12866 requires each agency to avoid regulations that duplicate other regulations. In response to this Executive Order, under Docket No. 95N–0192, in the **Federal Register** of April 3, 1996 (61 FR 14856 at 14859) FDA invited comments on the feasibility of developing performance-based regulations. Although the agency did not propose specific regulations in this area, it did suggest several possible performance measures for mammography and requested comments on their value and feasibility. The agency also invited the public to suggest other performance outcomes that might provide a basis for performance-based standards. FDA also invited comments on suggestions for other possible alternative approaches. While the standards that were proposed were not designed to be performance-based standards, there are elements of performance requirements throughout the final regulations. For example, most of the QC standards in the final regulations are performance based. The discussion in the proposal was to consider extending such performance criteria to areas not now covered by that type of requirement and to make the performance standards that had been proposed more general, thereby possibly reducing the burden on facilities.

1. General Comments

(Comment 28). Sixteen comments asserted that the goal of the quality mammography efforts by FDA should be to reduce burdens on the medical community by not requesting comments and review of additional regulations. Some of the comments stated that ACR should be the entity designated to define performance standards and that compliance with such standards should be voluntary. Five additional comments suggested that it was more appropriate for ACR and ARRT to oversee and govern mammography quality.

FDA notes that these comments are in conflict with the statutory provisions of the MQSA (42 U.S.C. 263b)), which mandate that the government have authority and responsibility to establish standards for the performance of quality mammography. However, in carrying out that mandate, FDA has solicited and considered comments from the members of the mammography community, including comments from ACR, ARRT, and members of NMQAAC.

(Comment 29). Several individual comments addressed the general issue of alternative approaches for quality mammography. One comment favored FDA's role in establishing and strengthening standards for quality mammography. Another suggested that FDA work with volunteers who have an interest in alternative compliance options in order to learn what is best.

Although FDA intends to continue to gather ideas and information from experts in the field, the agency believes that the opportunity for public review and comment on proposed regulations that will affect members of the mammography community is the most equitable approach and will minimize potential problems of ''standardization without representation.''

(Comment 30). Four comments addressed the issue of FDA establishing another set of interim rules, to be in effect while necessary research on performance outcomes-based standards was conducted, or simply going forward with the final regulations as proposed. These comments supported finalizing the proposed regulations and suggested change only if new technologies or alternative compliance options are identified at a later time.

Three comments focused on the cost of changing the regulations and discouraged change to the final regulations if any additional costs were to be borne by the mammography facilities.

FDA is sensitive to the issue of costs associated with the regulations and will keep this issue in mind whenever considering changes to the regulations.

(Comment 31). Two comments expressed concerns that the general aim of alternative approaches to achieve compliance would result in loopholes that would allow facilities *not* performing at acceptable levels to continue to perform substandard mammography.

The agency recognizes the importance of issuing performance standards that do not allow loopholes. As with provisions that specify the manner of compliance facilities must adopt, FDA intends to review performance-based approaches for potential gaps that could defeat efforts to achieve quality mammography.

(Comment 32). One comment stated that the ideas presented in the alternative approaches section are unworkable and were not discussed with the members of NMQAAC.

FDA acknowledges that NMQAAC did not have the opportunity to discuss the alternative approaches material before publication (61 FR 14856). However, NMQAAC members did have the opportunity to review this material and to make comments and recommendations at two meetings after the proposal was published.

Generally, the NMQAAC comments did not support increasing the number of performance-based standards at this time. They pointed out that the

proposed regulations were actually a mix of performance- and specification-based standards. While NMQAAC agreed that increased reliance on performance-based standards might have promise for the future, after further research is done, there are insufficient data at this time to base the entire set of standards on performance criteria.

(Comment 33). One comment stated that the current tests specified in the existing regulations are more thorough and complete than alternative performance approaches that were identified in the preamble to the proposed rules. A similar comment stated that the current tests should be used by all facilities, with the exception of those facilities that might develop improved, innovative strategies or methods. The comment recommended that these facilities apply to FDA for exemptions to use the innovative strategies or alternative methods. FDA notes that a process for accepting and reviewing such applications is provided by § 900.18.

An additional comment expressed support for the intent of Executive Order 12866, but at the same time argued that it is in the best interests of FDA to be more specific in the final rules about those instances where there are multiple methods or procedures to accomplish the same task. The comment further stated that it was unclear how the agency decided whether to use a performance outcome-based or a design-based requirement in a particular situation. A second comment expressed a similar opinion.

FDA notes that the comments on performance outcome-based standards discussed above and in the following pages point out many difficulties at the present time in establishing regulatory requirements to ensure quality mammography that are based totally on performance outcomes. However, the agency believes that in certain areas, for example, quality assurance, performance outcome standards can and should be established. In developing standards in a particular area, the agency first considered whether it was feasible to ensure quality in that area with performance-outcome standards. If it was not possible to issue adequate performance-outcome standards in that area, the agency then turned to design standards. Along those lines, FDA disagrees with the statement in the comment that specific-design standards should always be issued in cases where there are multiple ways of adequately achieving a particular task or goal. On the contrary, the agency believes that performance-outcome standards should be strongly considered in such areas in order to give facilities the flexibility to chose the method of achieving the goal that bests fits its particular circumstances, instead of requiring that all facilities follow the same path.

One other general comment similar to those of NMQAAC, asserted that it was premature to try to identify alternative performance-based approaches due to inadequate research and testing of these alternative methods at this time. Another comment indicated that FDA did not comply with Executive Order 12866 because the agency did not make a real effort to identify alternative approaches. Similarly, one comment argued that the FDA regulations ignored duplication with other regulations, although no examples were given.

FDA notes that it did include a number of possible performance outcomes measures in the proposal. There may be other possibilities of which the agency is unaware, but the fact that no alternatives were suggested by the author of these comments, or in any other comment, suggests that few, if any, other options are currently available. FDA further notes that the attempt to elicit public comment, recommendations, and opinions concerning performance-based standards through the proposal will not end its efforts to identify such alternatives. FDA is unable to respond to the criticism that its efforts duplicate other regulations in the absence of information on where the author of the comment believes this has occurred. However, HCFA has agreed to set aside its regulations in the mammography area and to accept FDA-certified facilities as meeting its requirements for reimbursement under Medicare and Medicaid. This eliminated one possible source of regulation duplication.

FDA strongly supports the use of performance standards, however, it recognizes that additional research is needed in the scientific community before it can support additional regulations based on performance outcomes. FDA encourages continued research in this area, and will actively work to develop performance standards in the future.

2. Performance Standards and Outcomes Measures Suggested in the Proposal

A large number of comments were received on the various performance outcomes measures identified as possible alternatives by FDA. These are reviewed in the following narrative in connection with the identified alternative.

3. Mammography Medical Outcomes Audit

(Comment 34). FDA in the preamble to the proposed rules, FDA suggested that the results of a mammography medical outcomes audit might be used as the basis for a performance-based standard for each mammography facility. A significant number of comments expressed concerns about one particular aspect of the audit, namely, requirements for patient followup that might be necessary to obtain outcomes data. The major issues raised were the cost of such followup and the lack of evidence that feedback about outcomes improves practitioner performance. The authors of the 10 comments believed that individual practitioners would never have sufficient cases to calculate meaningful statistical outcomes.

Concerns were also expressed that there were no protections for the confidentiality of outcomes data and that medical outcomes-based standards could motivate practitioners to avoid challenging or difficult cases. Eleven comments expressed objections to any performance standard that would require mammography facilities and interpreting physicians to collect followup data on films interpreted as negative or to require the calculation of statistics relating to sensitivity, specificity, or minimal cancer detection rates. One comment objected on the basis that requiring the collection of such data would imply that standards were required to force physicians to do the best possible job and that this was necessary because it was the norm for physicians to cheat or be dishonest. One comment expressed the view that use of cancer registries to accumulate data for monitoring outcomes was clumsy and expensive.

A related set of comments directed toward use of the positive predictive value (PPV) statistic as a measure of quality mammography performance was overwhelmingly negative. Nine comments pointed out that there are varying definitions of PPV and that this is not a measure familiar and understandable to the general public. The general consensus was that this statistic was not useful and should not be required to be published outside the physician's practice. Six respondents argued that it was completely unacceptable to use the physician's outcomes data as a measure of performance. Two comments expressed the viewpoint that collection of information about PPV was not appropriate because it was affected by many factors beyond the control of the facility. Three comments vehemently opposed the public disclosure of outcomes data, arguing that there would be a high likelihood of misinterpretation by the public and incentives for

facilities to falsify data. Two comments stated that data collection and review alone would not have any significant influence on radiologists' behavior, and consequently, that collection of statistical data was not worth the effort. Finally, one comment agreed that it would be valuable to find valid process and outcomes measures for mammography but concluded that it would be premature to focus on PPV, which is subject to influence by so many factors external to the radiologist.

In contrast to these negative comments on using the results of the mammography medical outcomes audit as the basis for performance standards, one comment strongly supported the idea of the medical audit as the basis for a performance standard and argued for the publication of such findings in order to ensure that the public had access to information that would allow them to select a reputable institution. Another supportive comment asserted that the agency should develop performance standards for medical outcomes audit statistics, which could then be used to evaluate physician performance. A third respondent urged that medical outcomes could and should be used as more comprehensive measures of competence and compliance. Another comment suggested that standardized values for sensitivity and specificity could support a reduction in personnel requirements for facilities that met the performance standards for these two statistics. One final comment applauded the possibility of change from specification of the manner of compliance to specification of performance objectives.

FDA observes that the majority of the comments received oppose the use of the results of the mammography medical outcomes audit as the basis for performance-based standards, at least at this time. The agency recognizes that the issues of the confidentiality of data collected and the limitations of PPV as an indicator of performance, and the other problems identified in the comments, are concerns that would have to be addressed before the audit could become the basis for performance-based standards. The agency has concluded that it is premature to establish performance standards based upon the mammography medical outcomes audit, primarily because the necessary data to establish such standards and to resolve the concerns expressed in the comments are not yet available.

FDA is aware that the National Cancer Institute's Breast Cancer Surveillance Consortium (NCI BCSC) has been actively engaged in research to understand the full effect of breast cancer screening on cancer outcomes through a collaborative effort with academic and community-based mammography facilities. Through linkages of data from mammography facilities with pathology data on cancer outcomes from population-based cancer registries, outcomes data will be correlated to interpretation. One of the goals of this research is to help establish realistic targets for mammography performance. FDA participates with the NCI BCSC and has staff expertise in the medical outcomes audit area to further assist standards development of outcomes measures. FDA will evaluate results from this research project as well as other projects to determine the best approach to promote improved mammography performance through performance-based outcome measures. FDA anticipates issuing regulations in the future that would have appropriate medical outcomes-based measures.

To this end, facilities are actively encouraged to develop their medical audit programs and pursue outcomes-based measures. Information to assist facilities in conducting and interpreting the mammography medical outcomes audit can be found in the medial literature. In addition, in 1994 the Agency for Health Care Policy and Research published, ''Quality Mammography: Clinical Practice Guidelines.'' This primer has a complete discussion of issues surrounding the medical audit and has references to aid facilities. Meanwhile, the suggestions contained in the comments to FDA's proposed rule supporting the use of the audit as a basis for performance standards will be considered by FDA in further efforts to develop performance-based standards. In addition, FDA specifically invites comments on this issue for future consideration. Please submit comments on this issue to the contact person listed above.

4. Performance-based or Proficiency Testing

With respect to personnel, FDA raised the possibility in the proposal that standards based on successfully passing proficiency tests might be the basis for replacement of design specification standards requiring certain levels of training and experience.

(Comment 35). The general consensus of 34 comments on proficiency testing was that such requirements would be excessive, unnecessary, costly, impractical, and duplicative of examinations already in place, such as those administered by the American Board of Medical Physics, the American Board of Radiology (ABR), and the American Board of Health Physics. Twenty comments criticized the use of performance-based standards in this area because they asserted that such standards are not yet developed to a level where they can substitute for current requirements. Two comments stated that it is better if FDA does not become involved in personnel performance-based standards as part of the MQSA. Rather, continuing medical education (CME) requirements as they currently exist should be satisfactory for this part of the education process. Three respondents indicated that the term ''performance-based testing'' is too vague and could include even such simple things as the radiologist's observation of the technologist performing an examination.

After reviewing these general comments and the specific ones that are discussed later in this document, FDA has concluded that it would be premature to establish general performance standards based on proficiency testing because there is no consensus among experts about what those standards should be or how they should be measured. The topic of proficiency testing for specific professional groups drew a number of responses varying in their level of support for such testing. Specific comments are noted and discussed as follows:

a. *Proficiency testing for radiologists*

(Comment 36). Proficiency testing for radiologists drew divergent responses. Three comments urged that FDA, in collaboration with NMQAAC, develop a proficiency test that physicians must pass prior to initiating the practice of mammography interpretation. Four additional comments favored proficiency testing for radiologists, but only as an initial requirement. Thirteen comments indicated unqualified support for proficiency testing for physicians. In contrast, five comments maintained that board certification could replace proficiency testing with intermittent retesting at 5- to 8-year intervals. Such examinations could be handled by the accreditation bodies. Another comment stated that random clinical image review at the time of the MQSA annual inspection could substitute for proficiency testing. Six comments agreed with the basic premise that performance evaluation is important in order to determine accurate standards but that more time is required to determine appropriate testing devices and standards. One comment stated that training and experience requirements for interpreting physicians should be sufficient and there was no need for periodic testing. Similarly, one comment stated that the

medical audit could function as a proficiency test for radiologists. Two comments expressed a total lack of support for proficiency testing, arguing that such testing is time consuming, costly, unnecessary, redundant, and not done in any other area of medicine. One comment stated that periodic proficiency testing is appropriate for nonradiologists reading mammograms but not for trained radiologists. In lieu of proficiency testing, this comment suggested a special certificate as part of designated continuing education courses as a simpler way to establish a measure of proficiency. One final comment stated that proficiency testing would impose undue hardship on the radiologist whose practice is not exclusively devoted to mammography. A total of 79 respondents argued that the cost of proficiency testing would be too high and that the additional expenses would be passed along to consumers.

FDA observes that support for proficiency testing for interpreting physicians is somewhat stronger than for proficiency testing in general, but that the majority of respondents still opposed the idea. Given the diversity of response to the possible use of proficiency testing for radiologists, and the fact that no existing tests were identified in the comments, FDA has concluded that it is not in the interest of quality mammography to mandate such testing at this time. The agency believes that proficiency testing for physicians, if feasible at all, would have to undergo further development before it could be the basis of a performance standard.

b. *Proficiency testing for technologists* (Comment 37). Three respondents stated that proficiency testing every 3 to 5 years would be beneficial to technologists. One additional comment concurred, but recommended testing every 2 years. Overall, however, there was a general lack of support in the comments for proficiency testing of technologists.

Sixty-one comments stated that such testing for technologists cannot be conducted objectively and also indicated that the final requirements were adequate to ensure the qualifications of technologists. Ten additional comments claimed that proficiency testing for technologists is impractical because of the lack of established criteria and the absence of an appropriate body to administer such tests. Three respondents argued that the medical audit served as a proxy proficiency test for technologists. Twenty comments stated that the proposed continuing education requirements were sufficient and it was not necessary to administer recertification examinations. Thirty-seven comments argued that technologist proficiency testing was redundant with the other initial and continuing education requirements.

One comment stated that at one time, the ARRT had considered adding a practical exam to its evaluation of mammography competency but deferred doing so until credible analyses would establish that such an examination would result in improved quality of performance. Four comments stated that proficiency testing for technologists would drive technologists away from the field of mammography. One comment expressed the view that annual testing was unnecessary because mammography does not change that rapidly. Another comment stated that a requirement for proficiency testing for technologists would have a negative impact on the availability of mammography in rural and mountainous regions. An additional respondent argued that the annual requirements for technologists are already excessive and the addition of competency or proficiency testing would simply raise costs or close mammography facilities. Four other comments expressed similar sentiments, stating that technologists already have to meet sufficient requirements, and the addition of proficiency testing would be excessive. Concerns also were raised about who would administer such testing and the method of payment. One comment urged that, if proficiency testing became a requirement for recertification, it should be offered at no cost to the technologist.

One comment argued that incompetent technologists could pass a proficiency test and further stated that proficiency testing was a measure of test-taking skills, not of mammographic competency. Two comments expressed the point of view that proficiency testing is useless and insulting. Several comments stated that recertification, if required in addition to continuing education, is redundant, time-consuming, and costly. These comments asserted that retesting is valuable only in instances of significant changes in the mammography modality. One comment pointed out that the ARDMS (a sonographer's organization not further identified) had tried to offer a practical examination, but abandoned the project because it proved too costly. The remaining comments were all generally opposed to proficiency testing for technologists. One comment suggested that a better way to evaluate technologists would be to require performance at a seminar that would assess their clinical competence. Another comment concurred with this viewpoint, saying that a written exam cannot measure competence in a hands-on field such as mammography. Finally, one comment argued that further examination is not necessary if the technologist remains active in the field of mammography and maintains proper licensure.

The agency is persuaded that regulations requiring such testing would be premature. FDA believes some of the objections raised, as with the objections to radiologist testing, can be addressed and overcome; e.g., to the extent comments argued that proficiency testing was duplicative of current training, education, and experience requirements, FDA could consider eliminating some of those requirements. However, the agency agrees with the general consensus expressed by the comments and concludes that proficiency testing for technologists currently cannot provide the basis for a performance standard.

c. *Proficiency testing for physicists* (Comment 38). The agency received 17 comments about this topic. Of the 17, 3 were in favor of proficiency testing for physicists, with 1 additional comment asserting that is would be possible to conduct such a test, but only at great cost. Other comments stated that proficiency testing for physicists was simply a bad idea. Two comments argued that the proposed standards of a written examination and a practical survey test were sufficient proficiency measures for physicists. Two comments stated that a doctorate in physical science and board certification in an appropriate medical physics sub-specialty provided a better assurance of professional integrity than written and practical examinations. Another comment suggested that it would be more appropriate for physicists' accreditation bodies to administer such tests because FDA lacked the necessary experience and knowledge in this area. One comment expressed concern about the possibility of computer errors if the examinations relied on computer programs for test administration and scoring. One comment recommended that the idea of a qualifying examination for physicists should be further explored, especially because the proposed regulations do not adequately address the issue of how detailed an annual survey should be.

One comment asked whether a performance-based standard would help physicists working at small institutions to meet the training requirements. Although it is possible that proficiency

testing could alleviate difficulties involving access to training for some physicists, FDA notes that it is not possible to determine whether such an approach would permit these physicists to qualify until such a time as the form and nature of a possible proficiency test is better known.

As with proficiency testing for interpreting physicians and radiologic technologists, the comments have persuaded FDA that it would be premature to require such testing for physicists as the basis of a performance standard. The agency, however, will continue to explore the feasibility of such testing for radiologists, technologists, and physicists.

5. Mammography Equipment and QC

The preamble to the proposals (61 FR 14860) suggested possible performance-based substitutes for equipment specification and QC testing in the proposed rule. One general comment recommended that FDA retain the existing QC tests as proposed to ensure adequate mammography equipment and QC. The author was of the opinion that one or two performance-based criteria would not be adequate to serve as QC measures.

a. *Phantom image testing*

FDA suggested that one possibility was that a more sophisticated phantom might be developed for use in a single QC test that would provide the same information on equipment performance as some or all of the separate tests and specifications. A performance-based standard predicated on test results using this phantom and falling within defined limits might provide the same assurance of image quality as a number of the design specifications and, therefore, could replace the design specifications in the regulations.

(Comment 39). One comment stated that it was possible to develop a single system test with an alternative phantom. The comment stated that one distinct advantage of a single system test would be to replace the present daily processor quality control (QC) test with sensitometry based on the actual light emission of the radiographic screen and at the same time check the performance of the rest of the imaging system. The comment stated that the final regulations should allow facilities and accreditation bodies to work together to adopt a suitable phantom to be used as a daily total system test. The majority of the comments received, however, were opposed to using phantom image testing as a comprehensive equipment test, even if such testing would permit alternative tests to be performed less frequently. There was strong support for FDA to implement the mammography performance and design requirements described in the proposed rules. Overall, a total of nine comments opposed use of the phantom as a daily test that would replace other QC tests. It was noted that more frequent use of the phantom would increase costs, would not yield an adequate measure of quality, would be useful only as a supplement to other QC tests, and would yield results that were highly variable. Three comments remarked that phantom testing is a good measure of quality but cannot replace all other QC tests. Finally, it was noted that the STEP test should be added to the phantom image analysis.

FDA observes that the general consensus of these comments is that it is unlikely that testing with a more sophisticated phantom, if one is made available through further research, will be an adequate substitute for other QC tests.

b. *Repeat rate*

Another measure that was suggested as a possible performance standard was the facility's repeat rate. Under the final regulations, a repeat rate is to be analyzed every 3 months, and include up to 250 examinations. In the preamble to the proposal (61 FR 14860), FDA asked for comments on the possibility of using the repeat analysis rate in some modified form, such as conducting the test continuously, as the basis for a performance standard. The agency also noted that such a use would have to take into account the possibility that the repeat rate could be altered through the acceptance by a mammography facility of all images of any quality performed.

(Comment 40). Responses to this possible alternative were generally negative. Three comments contended that the repeat rate could not serve as an alternative to existing equipment and QC tests. Specifically, it was noted that ongoing repeat analyses could not substitute for QC tests. Four comments raised concerns about the possibilities for altering or falsifying findings and lack of consistency within and between mammography facilities in performing repeat analyses. A related comment stated that technologists will not repeat images that should be redone if they think the repeated images will affect their job. This means poorer images may be submitted to radiologists for interpretation.

FDA recognizes the validity of the concerns raised by these comments and has concluded that a performance standard based on repeat rate analyses is not likely to enhance quality mammography nationwide.

c. *Clinical image review*

FDA identified clinical image review as a possible basis for performance-based standards. General comments regarding clinical image review for this purpose were largely unfavorable.

(Comment 41). Nine respondents argued that random selection of images for review is unnecessary because the review is conducted by the accreditation body. It is better therefore, these comments continued, to select previous images of the same patients to document improvements in image quality between examinations rather than random selection of images. Thirteen comments stated that the supervising radiologist ultimately is responsible for assessment of clinical image quality. Four comments questioned who would do the clinical image reviews for all facilities and suggested that this would require a new government agency in a time when government has been directed to downsize. Two comments stated that clinical image review is only useful as a learning tool in difficult cases and is not useful as a general test of proficiency.

Additional comments were received on the possibility of using clinical image review to evaluate the performance of the radiologic technologist. Twelve comments were openly opposed to clinical image review for assessment of technologists, arguing that it would require a large investment of effort and financial resources. One comment said that the radiologist, not the technologist, is responsible for the quality of images and, consequently, it would be inappropriate to use this as a performance assessment for technologists. Another comment expressed the point of view that clinical image review was unnecessary if technologists remain active in performing mammography and also maintain proper licensure.

The question of who would do the image reviews drew a number of comments. One comment said that clinical image review by technologists had been tried previously with poor success, although specifics about the problems were not mentioned. Nine comments asserted that clinical image review to assess technologist performance should be done under physician review, rather than by sending images to an outside bureaucracy, which would be very costly for facilities. Cost was raised as an issue by another respondent who argued that a facility with many mammography technologists would have many images out for review, which would be both costly and a threat to patient confidentiality. One comment suggested that the FDA inspector review

clinical images at the time of the annual MQSA inspection, rather than the facility submitting the images to some central point. Under this approach, technologists and radiologists would complete critique forms of their images to explain any difficulties or problems in taking or reading the films.

On the more positive side, twelve comments stated that clinical image review under the MQSA, combined with additional actions, would ensure proper mammography performance sufficient to assess technologists' clinical skills. The additional action suggested by 10 of these comments was yearly attendance at hands-on workshops, while another comment suggested periodic recertification examinations, and the 12th advocated use of repeat analysis. This last comment also suggested that such an evaluation could even substitute for the practice volume requirement for technologists in the proposal.

FDA observes that opinion is divided more evenly on the feasibility of using clinical image review as a performance standard for technologists than on the feasibility of the other possible bases for performance standards mentioned in the proposal. The major problem seems to be how to establish an effective system at a reasonable cost. Although clinical image review will not substitute for the radiologic technologist requirements being finalized in the regulations, FDA will continue to evaluate this issue in collaboration with the members of NMQAAC and other agencies involved with mammography QC.

6. General Observations

As discussed above, FDA sought public comment on the possibility of taking an alternative approach to assuring the quality of mammography nationwide. The alternative approach would be the greater use of performance-based standards in place of the primarily design specification standards established in the interim regulations and proposed for the final regulations. Several possible measures or mechanisms that could form the basis for performance-based standards were identified and the public was invited to comment on their feasibility and also to suggest other options. The agency also asked for comments on how it should proceed with regulation development if performance-based standards were considered feasible. If such standards could be developed relatively quickly, FDA could consider maintaining the interim standards and delaying the issuance of final regulations until performance-based standards were developed. Conversely, if the expected time for the development of performance-based standards was lengthy, in the interest of achieving additional improvement in mammography more rapidly, the agency might appropriately proceed with finalizing the proposed rules (as modified in response to public comment) and replace them at a later date with performance-based standards after the necessary research for those standards was complete.

(Comment 42). Only four comments addressed these questions directly and, as noted above, they urged FDA to proceed with publication of the final regulations. FDA also notes, as described above, that the comments on the possible mechanisms for performance-based standards identified by the agency were predominantly negative. Furthermore, none of the comments suggested any other possibilities for performance-based standards. This would seem to support the view that performance-based standards, if feasible, will require further research. Based on this, FDA concluded that it should proceed with the publication of these final regulations. If further research and development suggest that performance-based standards can replace these regulations, FDA will propose amendments to the MQSA rules.

*C. Scope § 900.1*

This section briefly summarized the content of the following regulatory sections. No comments were received and it was codified unchanged.

*D. Definitions § 900.2*

This section defines terms used in the regulations whose meaning would not be common knowledge or for which there exists more than one definition, making it necessary to specify which is to be used for the purposes of these regulations. Comments received on the definitions in the proposal are discussed first. This is followed by a consideration of comments that recommended adding new definitions or made other more general comments on the proposed definitions. Discussed third are definitions that have been added to, or changed from, those in the proposal due to changes in other parts of the regulations.

1. Comments on the Proposed Definitions

a. *General comments on several related definitions*

The following closely related definitions were included in the proposal in order to identify which consumer complaints must be considered by the facility and the accreditation bodies in the complaint process required by the MQSA:

- Adverse event
- Consumer
- Serious adverse event
- Serious complaint

The purpose of these definitions, as explained in the preamble to the proposal (61 FR 14863), is to ensure that serious complaints about the quality of the MQSA-related mammography services are adequately addressed without placing an undue burden on facilities and accreditation bodies by requiring extensive consideration for relatively minor complaints.

''Adverse event'' is defined to mean an undesirable experience associated with mammography activities within the scope of 42 U.S.C. 263b. Examples were included in the definition.

The definition of a ''consumer'' is intended to make it clear that a patient or a representative of the patient (for example, family members or referring physicians) can file complaints.

''Serious adverse event'' is defined to mean an adverse event that could significantly compromise clinical outcomes or for which a facility failed to take appropriate corrective action in a timely manner. Finally, ''serious complaint'' is defined to mean a report of a serious adverse event. Facilities, under § 900.12(h), and accreditation bodies, under § 900.4(g), are required to carry out specified activities in response to serious complaints.

(Comment 43). A number of general comments were received on these related definitions. One comment stated that using the severity levels outlined in current inspection procedures would be more applicable for complaint activities than the proposed definitions.

FDA disagrees with this comment. The severity levels used for the MQSA inspection program were developed for use by inspectors. They are too technical and not necessarily relevant for consumer complaint purposes.

(Comment 44). One comment recommended removing the terms ''adverse event'' and ''serious adverse event'' and the addition of the definition of ''complaint'' to mean the report of any undesirable experience associated with mammography activities. These experiences may include poor image quality, failure to send mammography reports within 30 days, or the use of personnel who do not meet regulatory requirements. Another comment also suggested adding a definition for complaint without specifying what it should be.

FDA believes that the definition offered by the first comment could result in complaints unrelated to the

MQSA (e.g., billing procedures) and complaints that would not ordinarily be considered serious by most patients (e.g., facility temperature) being forwarded to the accreditation bodies and FDA when they have the greatest chance for resolution at the facility. The final regulations require facilities to record all serious complaints. The facility will forward unresolved serious complaints to the accreditation body and/or FDA for further action. In addition, the agency notes that the definitions of ''adverse event'' and ''serious adverse event'' give examples of the kind of complaints that are within the parameters of the consumer complaint mechanism. All of the examples noted in the comment would fall within the scope of consumer complaints subject to further accreditation body and FDA review.

b. *Adverse event*

(Comment 45). One comment agreed that the definition of ''adverse event'' should include failure to send mammography reports in a timely fashion to the referring physician or self-referred patient, but argued that 30 days is an unreasonably long time for communication of adverse events. FDA notes that the 30-day period referenced in the definition is intended as the maximum amount of time that may elapse and that the regulations state that the results should be communicated as soon as possible.

This is discussed further in section III.L.3 of this document, where FDA's responses to comments received on §§ 900.12(c)(2) *Communication of mammography results to the patient*, and 900.12(c)(3) *Communication of mammography results to health care providers*, are given.

(Comment 46). Several comments requested greater clarity or additional explanation for the term ''poor image quality'' (used in the definition of adverse event), and FDA's criteria to determine when image quality is poor. The comment observed that the definition of poor image quality is likely to be very subjective.

FDA agrees that a single definition for poor image quality would be subjective and, therefore, has not included such a definition in order to give facilities and accreditation bodies the flexibility to evaluate such performance in a particular situation on a case-by-case basis. However, criteria to be considered by accreditation bodies in evaluating acceptable image quality are specified in § 900.4(c)(2). Consumers who decide to complain about poor image quality would generally have assistance from health professionals (for example, referring or consulting physicians, or accreditation body) in making this determination. In situations in which FDA has reason to believe image quality at a particular facility is poor, FDA may consult with accreditation bodies for additional mammography review in order to determine whether corrective or enforcement actions are appropriate.

c. *Serious adverse event*

The regulation defines ''serious adverse event'' as ''an adverse event that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.''

(Comment 47). Four comments recommended that the definition of ''serious adverse event'' should be revised. They stated that failure to take action on a nonserious event should not turn the event into a serious complaint. The comments recommended that ''serious complaint'' should be written to preclude common and potentially unavoidable complaints about mammography (e.g., compression hurts, room too cold).

FDA disagrees that the definition should be revised. Failure to take action on certain nonserious events may indeed result in a serious adverse event. For example, it is generally accepted that most compression complaints are considered to be minor. However, there may be instances in which compression is unusually severe and, therefore, the complaint would be considered serious. FDA believes the definition should remain flexible to allow for this type of situation.

(Comment 48). One comment suggested changing ''may significantly compromise clinical outcomes'' to ''has significantly compromised clinical outcomes.''

FDA disagrees. A primary goal of the consumer complaint mechanism is to improve mammography services by providing facilities with data and information they might not otherwise receive or analyze. It is preferable to correct a potentially serious situation before harm occurs, rather than after the harm has affected the patient.

d. *Serious complaint*

(Comment 49). A ''serious complaint'' is defined as ''a report of a serious adverse event.'' Two comments suggested that descriptions of the type of serious complaints to be reported to the accreditation body should be specified.

FDA agrees that additional descriptions will be helpful and intends to make such information available through guidance. The agency believes that making this information available in guidance, rather than in regulations, will give facilities, accreditation bodies, and FDA the flexibility to determine on a case-by-case basis whether or not an event should be classified as serious.

e. *Contact hour*

''Contact hour'' was defined in the proposal as an hour of training received through direct instruction.

(Comment 50). One comment recommended that it be defined as 50 minutes.

FDA is aware that in academic institutions an hour of didactic training is frequently only 50 minutes long. However, in clinical and continuing education situations, an hour of instruction is usually a full 60 minutes. Reducing the figure from 60 to 50 minutes would reduce the training requirements 16 percent. Because those training requirements were proposed at what are believed to be the minimum adequate levels, the agency did not change the definition.

f. *Direct instruction*

Direct instruction requires instructor-student interaction, either face-to-face or through examination.

(Comment 51). One comment stated that the definition is too vague, especially when compared to mammography equipment evaluation.

FDA disagrees. The agency believes the definition is sufficiently specific to give a clear idea of what is required, while also preserving the flexibility to accept possible new approaches to instruction.

g. *Direct supervision*

The definition of direct supervision was designed to permit ''trainees'' to lawfully obtain the experience in interpreting or producing mammograms or surveying mammography units that they needed to become qualified or requalified. At the same time, by having the trainee's work checked and, if necessary, corrected before any clinical care might be jeopardized, the patient's right to adequate quality mammography is protected.

(Comment 52). One comment supported this definition. A second comment asked if direct supervision was needed for ''nonqualified'' people doing the QC tests.

In accordance with 42 U.S.C. 263b(f)(1), personnel qualifications were established only for interpreting physicians, radiologic technologists, and medical physicists. As a result, tests performed by medical physicist ''trainees'' would have to be done under this definition of direct supervision, although tests performed by QC technologist ''trainees'' would not. However, the agency notes that § 900.12(d)(1)(iv) makes the QC technologist responsible for ensuring the quality of performance of those

doing QC tests. The definition of QC technologist in § 900.2(pp) requires the QC technologists to meet the requirements for a radiologic technologist, including training in quality assurance/QC. Taken together, these requirements provide for a level of supervision similar to that provided under this definition.

h. *Facility*

The definition of ''facility'' is provided by the law itself in 42 U.S.C. 263b(a)(3). It includes a variety of types of locations where mammograms are produced, processed, or interpreted.

(Comment 53). Three comments either inquired if processing and interpreting facilities would have to be certified and inspected or asked that these facilities be excluded from the requirements. The law defines locations where mammograms are processed or interpreted, and where mammograms are produced, as facilities (42 U.S.C. 263b(a)(3)). The agency's approach under the interim regulations, which is expected to continue under the final regulations, has been a systems approach. The facility producing the mammograms receives the certificate and is responsible for ensuring that the facilities at which their mammograms are processed and interpreted, if separate, meet the applicable quality standards. This is consistent with the statutory provision that requires the facility performing the mammography to be responsible for meeting quality standards (42 U.S.C. 263b(a)(3)(B)). FDA has not set up a separate certification and inspection system for facilities that process or interpret only. However, because a certification system for ''partial'' providers may have some advantages for such facilities, the agency may consider such an approach in the future.

(Comment 54). Two comments requested that the definition be expanded to address situations involving multiple locations under the same certificate or temporary locations where a unit (stationary, portable, or mobile) is used more than a minimum number of days.

FDA's experience under the interim regulations shows there is wide variety in the locations at which mammography is performed and in the corporate and business relationships among these locations. Presently, such situations are handled on a case-by-case basis in consultation with the facilities and accreditation bodies involved. The agency believes that it is essential that this flexibility be maintained and that it would be unduly restrictive to prescribe permissible locality arrangements in regulation.

i. *First allowable time*

The proposal defined ''first allowable time'' as the earliest time a physician is eligible to take the diagnostic radiology boards of an eligible certifying body. Because the ''first allowable time'' a resident physician becomes eligible to take the boards may vary with the certifying body, the definition cannot be more specific. If a resident physician wishes to use the exemption from the initial experience requirement described in § 900.12(a)(1)(iii)(B), it is the physician's responsibility to ascertain the requirements of the body by which he or she wishes to become certified and to seek that certification as soon as he or she becomes eligible to do so.

(Comment 55). Three comments stated that this definition was unclear and were unsure how or why this related to resident physicians who would be interpreting 240 mammograms during a 6-month period. NMQAAC also stated that the concept of ''first allowable time'' required further explanation.

This term is used in § 900.12(a)(1)(iii)(B). That provision is an exemption that allows resident physicians to interpret the 240 mammograms required for initial experience in any 6-month period during the last 2 years of their residency program (rather than during the last 6 months immediately prior to the date that the physician qualifies as an interpreting physician as required under § 900.12(a)(1)(D)). This exemption is available as long as these physicians become board certified the first time they are eligible. This provision allows residency programs to be flexible in scheduling training for their resident physicians and eliminates the need to put all senior resident physicians on their mammography rotation during the last 6 months of their program.

(Comment 56). Two comments stated that because the ''first allowable time'' may vary with the certifying body, a more uniform standard would be preferable.

FDA believes that the term ''first allowable time'' must be defined as proposed in order to allow flexibility, because certifying bodies differ in the scheduling of their examinations. Anything more proscriptive could penalize future resident physicians if the certifying body wished to change its examination schedule.

j. *Lead interpreting physician*

This term was included in the proposal to identify the interpreting physician who has the general responsibility for ensuring that the facility meets the quality assurance requirements.

(Comment 57). One comment stated that the definition was not needed because this person is easily identified, while a second comment wanted the term changed to supervising interpreting physician.

FDA agrees that in most facilities the person with this responsibility can be easily identified, but also believes there is an advantage in having a term that can be used to designate and reference this individual, both for the benefit of the employee and patients of the facilities and for the accreditation bodies and the government regulators. The possibility of using ''supervising'' was discussed with NMQAAC but was rejected out of concern about possible confusion between this individual and administrative supervisors who may have different responsibilities.

k. *Mammographic modality*

''Modality,'' as proposed, means a technology, within the scope of 42 U.S.C. 263b, for radiography of the breast. Screen-film and xeromammography were given as examples of a modality. In fact, at present, they are the only examples in general use.

(Comment 58). Two comments stated that the term modality has other uses in medicine and that the definition could be confusing to facilities. Twelve other comments also found the term unclear.

FDA notes that NMQAAC spent some time discussing other possible terms that could be used before concluding that this was the most appropriate. The agency is aware that the term modality is used in different ways in different areas, which is why a definition of its meaning with respect to the MQSA is needed. In an effort to distinguish it further from the other meanings of modality, FDA has changed the name of the term being defined from ''modality'' to ''mammographic modality.'' The definition now appears in the final regulations at § 900.2(z).

(Comment 59). Two comments recommended that the term ''modality'' be replaced with ''specialized techniques in mammography.''

FDA did not accept this suggestion because both ''techniques'' and ''specialized techniques'' already have a variety of meanings in radiology and the agency concluded that the recommended change would increase rather than reduce confusion.

(Comment 60). Nine comments suggested that the definition be broadened to include other technology. Stereotactic, ultrasound, digital, nuclear medicine, Magnetic Resonance Imaging (MRI), and CT were all suggested for addition.

FDA does not believe that the definition should be broadened. The definition is intended to clarify training requirements for personnel providing mammography services. These individuals are required to have training in each mammographic modality with which they work. Because ultrasound, nuclear medicine, and MRI fall outside the statutory definition of mammography as radiography of the breast, the agency cannot include training related to those technologies as part of the regulatory requirements. Digital, CT, and stereotactic do fall under the authority granted by 42 U.S.C. 263b but have been temporarily exempted from the regulatory requirements. When and if training and other requirements related to these technologies are issued, the proposed definition will not delay such requirements from taking effect for those modalities.

(Comment 61). One comment recommended that xeromammography be excluded from the definition because it produced less than optimal mammograms at a higher dose.

FDA agrees that there have been problems with the use of xeromammography and notes that these problems have led to its near disappearance. However, the effect of removing xeromammography from the definition would be to exempt those who use the technology from having to obtain training. FDA expects such a change would increase, not decrease, the problems with the modality.

l. *Mammography*

This definition incorporates the definition of mammography as ''radiography of the breast'' provided by 42 U.S.C. 263b(a)(6), but temporarily excludes from the quality standards radiography of the breast performed in interventional mammography or with an investigational mammography device during a scientific study conducted in accordance with FDA's investigational device exemption regulations.

(Comment 62). One comment suggested that ''for the purposes of these regulations'' should be inserted in this definition.

FDA believes that it is well understood that all definitions that appear with any regulation are for the purposes of those regulations.

(Comment 63). Another comment suggested expanding the wording of the definition to specifically mention X-ray radiation and several types of image receptors. FDA notes that the term radiography implies the use of X-rays.

The agency further notes that if the changes were made, and a new, yet unimagined type of image receptor was approved following investigational device studies, the definition would have to be amended before the new device could be put into general use. To avoid such a delay in the use of an advance in image receptor technology, the agency has retained the proposed general definition.

m. *Exclusion of interventional mammography*

In the proposal (61 FR 14862), FDA temporarily excluded interventional mammography (radiography performed during invasive interventions for localizations or biopsy procedures) from the definition of mammography. This had the effect of exempting such mammography from the requirements of the regulations. A similar exemption has been in effect under the September 30, 1994, amendments to the interim regulations (59 FR 49808–49813). The basis for the exclusion, as explained in the preamble to the proposal (61 FR 14862), was the agency's belief that science had not advanced to the point where effective national quality standards could be developed for these devices.

(Comment 64). Over 90 comments supported the exclusion of interventional mammography. Many of these agreed that there currently is no consensus with respect to appropriate standards for stereotactic units, and until regulations based on scientific data can be developed, it is inappropriate to include interventional procedures within the scope of the regulations. In addition, the comments stated that surgeons have extensive experience in dealing with breast disease and breast biopsy and they are best suited to manage the patient. These comments noted that many surgeons have had extensive experience performing stereotactically guided breast biopsies and have achieved good results with this procedure. Others wrote that in this procedure, the surgeon knows that the lesion is present and is merely using stereotactic images to guide the needle to the proper position for biopsy. Other comments stated that while radiologists have only one method to biopsy the breast, surgeons have several options and can offer the patient the best biopsy option for her clinical status. Some comments stated that surgeons have a long history of providing followup care for patients and for many years have used radiographic equipment in the operating room and are familiar with its use. Several comments said that surgeons have used mammography for many years in the diagnosis and treatment planning for breast cancer patients. Still others said that these biopsy procedures will evolve into therapeutic procedures that are best handled by the surgeon and that surgeons are best equipped to handle any followup or complications associated with these biopsy procedures.

NMQAAC and over 100 comments opposed the exclusion of interventional mammography. Many of these asserted that it is counterproductive to set quality standards for mammographic diagnosis while having none for mammographically guided invasive breast procedures and that only interpreting physicians have the expertise and experience necessary to perform this procedure. Authors of other comments wrote that interpreting physicians have experience dealing with the quality assurance and QC issues necessary to maintain stereotactic biopsy equipment and that the failure to regulate this procedure places the public at risk. Some said that the lack of adequate mammographic training could lead to the lesion in question being missed during tissue sampling and that the abilities and training required to localize a small subtle suspicious area are the same as those for interpreting a mammogram. Other comments stated that only interpreting physicians will be able to interpret the original mammograms to determine if a needle biopsy is appropriate.

FDA agrees with the comments stating that interventional mammography can be of great use in the evaluation of breast disease, but only if optimally performed. Until recently, the science had not advanced to the point where effective national quality standards could be developed for these procedures. Since the publication of the proposed regulations on April 3, 1996, significant progress has occurred in the professional community and FDA now believes that there is enough information to begin the development of interventional mammographic regulations. However, that development requires a comprehensive and careful approach that addresses all the factors involved in such procedures. The agency has already begun the development process by bringing this issue before NMQAAC during its October 1996 meeting and is continuing to gather information and data. Although the agency has concluded that the final regulations should exclude coverage of interventional mammography, FDA expects to propose regulations covering all aspects of interventional mammography in the near future.

n. *Exclusion of investigational devices*

In the proposal, FDA also excluded from the definition of mammography,

and thus from the regulatory requirements, investigational mammography devices that were being evaluated in accordance with FDA's investigational device exemption regulations in 21 CFR part 812. This provision extended the exclusion for investigational devices previously established under the September 30, 1994, amendments to the interim regulations. The agency believes that it is obvious that it would be premature to establish standards for devices still in the experimental stage. FDA also believes that the precautions built into the agency's general investigational device exemption regulations provide adequate protection for the public health during the use of these devices. However, the agency made clear in the preamble to the proposal (61 FR 14862) that any conventional mammography device used during the scientific study to provide baseline data for evaluating the safety and efficacy of the investigational device was not within the scope of the exclusion and would have to meet the MQSA requirements.

(Comment 65). Two comments stated that the wording of this section would make MRI for mammography investigations or use of full field digital mammography illegal, unless they are performed by a radiologist specializing in mammography.

MRI is not radiography of the breast and, therefore, does not come under the definition of mammography. Similarly, investigational studies, such as those involving full field digital mammography, are specifically excluded under the definition of mammography in § 900.2(z)(2) of the final regulations. FDA concludes, therefore, that the regulations will not prevent such research from occurring. However, any conventional mammography performed as part of a study is not excluded and does have to meet all the requirements of the final regulations. FDA has modified the definition to clarify this issue.

o. *Mammography medical outcomes audit*

''Mammography medical outcomes audit'' means a systematic collection of mammography results and the comparison of those results with outcomes data.

(Comment 66). One comment stated that the term ''medical audit'' was self-explanatory and did not need a definition.

FDA disagrees. There are many different working definitions of this term being used in the professional community. FDA's definition of what minimally constitutes a mammography medical outcomes audit is for the purposes of the MQSA requirements and may be different from recommended guidelines and definitions of other organizations.

p. *Mammography unit or units*

The definition for ''mammography unit or units'' is an assemblage of components for the production of X-rays for use during mammography. Several components were listed.

(Comment 67). Two comments suggested that compression device, breast support, and components associated with the image receptor and grid be added to the list.

These suggestions would not fit the general criterion of a component for the production of X-rays and the agency is not adding them to the list.

q. *Mean optical density*

''Mean optical density'' was defined as the average of the optical densities measured for phantom thicknesses of 2 to 6 centimeters (cm) using kilovolt peak (kVp) values clinically appropriate for the thicknesses.

(Comment 68). Three comments were received on this definition. One suggested that the thickness range should be changed to 3 to 7 cm. A second also supported a 3 to 7 cm range, but stated it would be prudent to check at 2 and 8 cm as well. The third comment stated that, because the thicknesses chosen could influence the result, the definition should specify the thicknesses to be used. The comment further suggested that 2, 4, and 6 cm should be used.

This definition is used in connection with a QC test of Automatic Exposure Control performance. The test procedures recommended by the ACR manuals and incorporated by reference into the interim regulations requires the use of 2, 4, and 6 cm thicknesses. The agency agrees with the third comment that it would be of value to add the exact thicknesses to the definition and has done so. FDA does not believe there is justification for changing the range of thicknesses used in this standard test, as suggested by the other two comments.

r. *Medical physicist*

''Medical physicist'' is defined as a person trained in evaluating the performance of mammography equipment and quality assurance programs and who meets the requirements of § 900.12(a)(3).

(Comment 69). One comment stated that the MQSA does not provide statutory authority to FDA to define the profession of medical physicist.

It is not FDA's intention to define the profession of medical physicist in general and the agency also agrees that it lacks the authority to do so. However, the MQSA requires that the agency establish qualifications for those medical physicists providing mammography services to mammography facilities (42 U.S.C. 263b(f)(1)(E) and (F)). This provides both the authority and responsibility to define ''medical physicist'' for the purpose of these regulations. Again, this definition applies only to medical physicists who wish to provide services to mammography facilities under the MQSA and not to the profession as a whole.

s. *Multi-reading*

''Double reading,'' defined as two or more interpreting physicians interpreting the same clinical image, was included in the proposal to describe one of the options that interpreting physicians can use to meet the experience requirements.

(Comment 70). Several comments, including a consensus of NMQAAC, requested further clarification of this term. Confusion apparently has arisen due to the fact that ''double reading'' commonly is used to describe the situation where a mammogram is read by two interpreting physicians in an attempt to improve the accuracy of the interpretation. Two comments, including a consensus comment from NMQAAC, suggested that another term be used to describe multiple interpretation as it applies to the final regulations.

In response to these comments, FDA has substituted the term ''multi-read'' to describe interpretation of mammograms by two or more physicians. Multi-reading can be used by physicians to meet continuing experience requirements. Multi-reading can also be used by physicians to meet initial and/or requalification requirements if it is done under direct supervision.

(Comment 71). Some of the comments incorrectly assumed that FDA was forcing facilities to have all their mammograms read by two interpreting physicians.

While facilities are free to perform this type of ''multi-reading'' as a means to improve accuracy, FDA does not require that any mammogram be read by more than one interpreting physician.

(Comment 72). One comment suggested adding the words ''that has not been marked as to possible pathology'' at the end of the definition of ''double read'' (now changed to multi-read).

FDA disagrees and believes that an interpreting physician benefits from reviewing mammograms, even those that have been marked by another physician. Requiring the removal of such marks would be overly burdensome and might even be

detrimental to the patient if the original marks were not put back on the images.

(Comment 73). One comment requested clarification as to whether physicians must independently interpret the same clinical image, or is it within the intent of the definition to include two or more physicians in consultation interpreting the image together.

FDA intends the concept of ''multi-reading'' to include both independent and consultative reading. If the multi-reading is done under direct supervision, there must be a consultative component to the supervision.

t. *Patient*

In the proposal, FDA used ''examinee'' to refer to any individual undergoing a mammography examination. This was a change from the term ''patient,'' which was used in the interim regulations. As explained in the preamble to the proposal (61 FR 14862), the change was made in recognition of the fact that most individuals who undergo mammography are not ill and do not have a condition requiring medical care.

(Comment 74). Eighteen comments stated that it was not necessary to replace ''patient'' with ''examinee,'' because patient is a term used universally. One comment objected to the proposed use of ''examinee'' and preferred ''patient'' because ''patient'' conveys the ethical protections of a doctor-patient relationship, confers malpractice protection, and ensures that third party payers recognize the examination as required care. One comment agreed with the definition of examinee and the inclusion of self-referred persons.

NMQAAC discussed these comments and there was general consensus to recommend that FDA use the term ''patient,'' provided the definition would include people who did not have health care providers and people without medical symptoms. Finally it should be noted that the MQSA uses the term patient. In light of these comments, FDA has decided to return to the use of ''patient,'' which is defined in the final regulations as anyone undergoing a mammographic procedure.

u. *Phantom*

''Phantom'' is defined as a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast tissue and disease.

(Comment 75). One comment on this definition requested that FDA specify the phantom contents and measurements. A second comment urged FDA not to change the current phantom unless the new phantom decreased the frequency of other testing.

FDA believes that the accreditation bodies should establish the phantom specifications and related performance criteria, rather than the agency establishing them through regulation. However, as part of its responsibilities for accreditation body approval and oversight, FDA will examine each body's phantom specifications and performance requirements to ensure that they are substantially the same among different accreditation bodies.

FDA believes that the second comment was in response to the suggestion that a more sophisticated phantom might facilitate the establishment of performance outcomes standards based on the new phantom's use that would take the place of several of the existing tests. This issue was discussed previously with other comments on that subject under section III.B of this document, where the agency concluded that performance standards based on a new phantom were not practical at this time.

v. *Physical science*

''Physical science'' means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

(Comment 76). One comment received on this definition stated that the engineering part of this definition should be limited to electrical and nuclear engineering only, while a second comment opposed the inclusion of engineering and chemistry at all.

FDA notes that this term is used to establish the qualifications to be met by medical physicists, which include a degree in the physical sciences on an appropriate level. The purpose of that part of the requirements is to ensure that the individual has a general familiarity with the scientific concepts, calculations, and techniques that provide a basis for understanding and completing more specialized work in medical physics, not that he or she has already achieved the training in medical physics. The agency further notes that this general requirement is reinforced with a more specific requirement for training in physics. Because meeting these two requirements provides an adequate foundation for meeting the more specialized medical physics requirements, the agency does not believe the definition needs to be narrowed by eliminating the fields suggested in the comments.

w. *Positive mammogram*

''Positive mammogram'' means a mammogram that has an overall assessment of findings that are either ''suspicious'' or ''highly suggestive of malignancy.''

(Comment 77). One comment stated that the term positive mammogram was self-explanatory and did not need a definition. FDA disagrees. There are many different working definitions of this term being used in the professional community. Because the final regulations require all positive mammograms to be entered into the facility's medical audit system, it is necessary to retain a definition of ''positive mammogram'' in order to clarify the scope of the audit.

x. *QC technologist*

This term was defined to mean the individual who is responsible for the segments of the quality assurance program that are not the responsibility of the lead interpreting physician or the medical physicist. In general, this responsibility consists of the routine QC testing and some data analysis and corrective actions related to the results of that testing.

(Comment 78). One comment stated that it is not necessary to identify or define this position because the person with this responsibility is easily identified.

FDA does not agree with this comment for the same reason it disagreed with the similar comment about the definition of lead interpreting physician. In addition, the title of QC technologist is already widely used in mammography facilities.

This definition was changed, however, as a result of discussions at the January 1997 NMQAAC meeting. It is often possible for a single individual to perform the duties of a QC technologist for an entire radiology facility. That individual ordinarily is a technologist, but may not meet the qualifications to do mammography. At early meetings, NMQAAC had agreed that this person should be a qualified technologist, but did not necessarily have to be qualified to perform mammography. This would avoid the possibility that the mammography department of a radiology facility might have to have its own QC technologist, thus forcing the facility to assign two persons to meet the responsibilities previously handled by one. NMQAAC reconsidered its position at the January 1997 meeting, however, and concluded that the advantages of having the QC technologist in the mammography department be qualified to do mammography outweighed the possible extra costs. FDA accepted NMQAAC's advice on this matter and changed the wording in the definition to require the QC technologist to meet all the qualifications in § 900.12(a)(2) for

radiologic technologists doing mammography.

(Comment 79). Three comments disagreed with the proposed definition because it barred qualified biomedical engineers, manufacturer's representatives, and other individuals the authors believed were qualified from serving as QC technologists. Although NMQAAC has changed its position from time to time on whether the QC technologist must be qualified to do mammography, it has never wavered from its advice that the individual in this position should be a radiologic technologist. FDA concurs with that view. However, as discussed below in connection with the quality assurance requirements under § 900.12(d)(1)(iv), the final regulations permit nontechnologists to perform certain QC tasks as long as the QC technologist ensures that the performance is adequate.

y. *Traceable to a national standard*

Traceability refers to the ability to show that an instrument has been calibrated by a process that eventually led back to a standard established by the National Institute of Standards and Technology (NIST).

(Comment 80). A number of comments requested further clarification of traceability. A few comments requested that the requirement for annual calibration be changed to every 3 years.

In response to these comments and after discussion with calibration experts, FDA has revised the definition of traceability. The term itself has been changed to ''traceable to a national standard'' to more clearly reflect what is needed. Other changes have clarified that the ultimate source of the calibration may be either NIST or a calibration facility that participates in a proficiency program with NIST at least once every 2 years during which the calibration facility achieves agreement within + 3 percent of the NIST standard at mammography energy levels.

2. New Definitions Suggested by the Comments

a. *Category I*

(Comment 81). Several comments suggested that the meaning of the term ''Category I,'' as used in the regulations, was unclear.

In response, FDA has defined Category I, at § 900.2(g), to mean medical educational activities that have been designated as Category I by the Accreditation Council for Continuing Medical Education, the American Osteopathic Association, a State medical society, or an equivalent organization.

b. *Contact mammography*

(Comment 82). One comment recommended that this term from the final regulations should be defined. However, in the revisions of the regulations following the public comments, this term has been eliminated, so a definition is no longer needed.

c. *Continuing education unit*

(Comment 83). One comment warned that it would be difficult to interpret the personnel training requirements if the term continuing education unit was not defined.

FDA agrees with this comment and has added a new § 900.2(l), which states that continuing education unit or continuing education credit means 1 contact hour.

d. *Diagnostic and screening mammography*

(Comment 84). Over 30 comments stated that diagnostic and screening mammography should be defined and asserted that vacillation over these definitions only confuses the public and those who are to measure outcomes.

As explained in the proposed rule (61 FR 14862), FDA is eliminating these terms from the definitions section because differences of opinion within the professional community regarding the distinction between these two types of mammography procedures remain unresolved. These terms can have different meanings depending upon their context. For example, HCFA has defined screening and diagnostic mammography for claim processing purposes. AHCPR has defined these terms in their guidelines for medical audits. On the other hand, some facilities do not distinguish between screening and diagnostic mammography. Facilities also differ on categorizing certain circumstances as screening or diagnostic, as in the example of a healthy, asymptomatic woman with breast implants who has diagnostic views performed during ''routine screening.'' The terms screening and diagnostic mammography, along with other terms and definitions associated with the medical audit, are in the process of obtaining consensus within the scientific community. At present, FDA recommends that each facility choose and consistently utilize HCFA, AHCPR, or other definitions in the medical literature for medical audit purposes.

e. *Established operating level*

(Comment 85). One comment noted that this term was used in connection with a number of QC tests and suggested that it be defined as ''the single point for a particular quality assurance parameter set by the lead interpreting physician.''

FDA agrees that a definition of established operating level is needed and has added, at § 900.2(p), that ''established operating level means the value of a particular quality assurance parameter that has been established as acceptable by the facility's quality assurance program.'' This definition indicates that the level should not be merely set but also should be determined to be acceptable. The responsibility for making that determination will belong primarily to the lead interpreting physician, as the comment suggested. However, the definition being issued refers to acceptance as part of the entire quality assurance program because additional facility and FDA personnel also may be consulted when the level is established.

f. *Image receptor*

(Comment 86). Two comments suggested that a definition of image receptor be included in the final regulations. FDA notes that there is a general understanding within the radiology and general medical community of what this means and if a specific definition is needed, one is already available in 21 CFR 1020.30(b). The agency does not believe that it needs to be repeated here.

g. *Image receptor support device*

(Comment 87). One comment suggested that a definition of image receptor support device as that part of the mammography X-ray unit that is designed by the manufacturer to hold the cassette be added to clarify § 900.12(b)(5).

FDA agrees that this is a useful suggestion. However, as a result of other revisions that have been made to the proposal, the term ''image receptor support device'' is no longer used in the regulations and, therefore, a definition is no longer needed.

h. *Laterality*

(Comment 88). Several comments found the meaning of the term ''laterality,'' as used in the regulations, to be unclear.

In response to these comments, FDA has defined laterality, at § 900.2(w), to mean the designation of either the right or left breast.

i. *Mammography equipment*

(Comment 89). One comment suggested that a definition of ''mammography equipment'' should be added and further suggested that the definition include all physical components of a mammography facility needed to produce an interpretable film. The author believed that this would more clearly define the components that the physicist would need to include in the required ''survey'' of ''mammography equipment'' for which

he or she has been assigned responsibility under § 900.12(d)(1)(iii).

FDA considered the possibility of adding this definition, but notes that § 900.12(e)(9) already establishes the evaluations that, at a minimum, are to be included in the survey. Because of this, the agency decided that an additional definition was not needed.

j. *Mobile unit*

(Comment 90). Three comments suggested that mobile units should be defined in such a way as to clarify when mammography units used under a variety of different circumstances are to be included in this category.

FDA notes that the term mobile unit is relevant to compliance with these regulations only in determining when the additional testing required by § 900.12(e)(7) needs to be performed. Under § 900.12(e)(7), a mobile unit is one that is used to produce mammograms at more than one location. The agency believes § 900.12(e)(7) makes it sufficiently clear when the additional testing is needed.

k. *Quality assurance, quality assurance program, and QC*

(Comment 91). Two comments recommended that these terms be defined. FDA notes that one or more of these terms have been defined in 21 CFR 1000.55, in the ACR Quality Assurance manuals, or by various other authorities. While the wording of these definitions may vary, the basic concepts are the same and are widely understood. The agency does not believe that they need to be defined again.

l. *Technique chart*

(Comment 92). One comment among those that suggested that a technique chart should be part of the quality assurance manual also noted that this would require defining technique chart. The comment also made some suggestions for the definition.

FDA notes that, as will be discussed with other comments related to quality assurance records required under § 900.12(d)(2), a technique chart is not being required to be included in the facility's quality assurance manual. Because the term is not used in the regulations, a definition is not needed.

m. *Other comments on the proposed definitions*

(Comment 93). Thirteen identical comments wanted the quality assurance definitions changed, stating that, ''it is objectionable to have the FDA creating definitions of medical terms not agreed on by physicians.''

Quality assurance is not defined in the regulations and, as discussed above, the agency does not believe such a definition is needed. From other information in the letters containing the comments, it appears that they are actually referring to specific definitions discussed under the heading of ''Quality Assurance'' in the preamble to the proposal. There were four such definitions: ''lead interpreting physician,'' ''QC technologist,'' ''time cycle,'' and ''traceability.''

FDA agrees that, to the extent possible, the agency should adopt definitions for medical terms that have widespread agreement among physicians. In fact, QC technologist, as discussed above, is already a title widely used in facilities and in the ACR manuals. It appears that medical facilities have already reached consensus on its use as an administrative title, although there may be differences on the necessary qualifications of such individuals.

The agency does not agree that the other three terms are medical terms whose definitions require agreement among physicians. ''Time cycle'' and ''traceability'' are technical terms related to the film development time and the calibration of radiation measuring instruments. These are not terms that physicians use regularly or about which they are likely to discuss and reach consensus. The remaining term, lead interpreting physician, is an administrative term, not a medical one. As discussed previously, this term has been defined as the designation of an individual physician at each facility who has certain responsibilities under these regulations; that identification will make it easier for facilities, accreditation bodies, and government regulators to ensure and monitor compliance with the MQSA standards.

3. New or Changed Definitions Made Necessary by Changes in the Regulations

a. *Air kerma and kerma*

The Omnibus Trade and Competitiveness Act of 1988 amended the Metric Conversion Act of 1975 to require each Federal agency to use the International Systems of Units (SI) in its activities. The SI is also known as the metric system although it makes use of only some of the metric quantities and units. In accordance with this requirement, a memorandum dated March 19, 1990, from FDA's Associate Commissioners of Regulatory Affairs and Public Affairs, established the FDA policy for the use of SI metric measurement. Since 1990, FDA has been undergoing a transition to SI quantities and units in its regulatory activities. To this end, air kerma, which is an SI quantity, has been introduced as a replacement for the quantity of exposure previously referenced in § 900.12(e)(5)(v). Definitions of ''air kerma'' and ''kerma'' were also added as §§ 900.2(d) and 900.2(v), respectively, in the final regulations.

b. *Calendar quarter*

To give facilities more flexibility in maintaining their records on personnel qualifications, changes were made in several provisions of § 900.12(a). These changes allow the facility to use a variety of methods to calculate the time periods necessary to establish compliance with personnel requirements. In calculating these time periods, the facility may designate any one of the following as the endpoint for the period of time used to determine if their staff met the continuing education and experience requirements: (1) The date of the inspection; (2) the last day of the last calendar quarter before the inspection; or (3) any date in between those two. To avoid any misunderstandings, FDA added a definition of calendar quarter, under § 900.2(f), that establishes the endpoints of the 4 quarters as March 31, June 30, September 30, and December 31.

c. *Interim regulations*

Reference was made to the interim regulations several times in the final regulations. For the benefit of those unfamiliar with those regulations, FDA defined them by citing, under § 900.2(t) of the final regulations, the **Federal Register** publication of December 21, 1993, as amended on September 30, 1994.

d. *Interpreting physician*

This definition was modified from the proposed definition by adding the term ''licensed'' in order to clarify the intent of the statute that the physician maintain a valid State license to practice medicine.

e. *Qualified instructor*

During the revisions of the training requirements for radiologic technologists, the term ''qualified individual'' and its definition in § 900.12(a)(2)(ii) were replaced by the term ''qualified instructor'' in referring to the individuals providing the training and the category of such individuals was expanded. These changes made it necessary to add, as § 900.2(oo), a definition of ''qualified instructor'' as an individual whose training and experience adequately prepares him or her to carry out specified training assignments. The new definition also includes examples.

f. *Standard breast*

Although the term standard breast was used and defined at several points in the proposed regulations, it had not been included in the definitions section. It has now been added as § 900.2(uu) in the final regulations.

*E. The Accreditation Body Application (§ 900.3)*

In this section, FDA proposed procedures to be followed by organizations or agencies applying to become FDA-approved accreditation bodies. It also proposed criteria for evaluation and approval of prospective accreditation bodies.

1. General Comments on the Accreditation Process

(Comment 94). Several comments supported portions of the rule, and the initial accreditation process in general, stating that it had elevated the quality of many facilities under the interim regulations. Other comments, including some from members of NMQAAC, expressed a variety of concerns, including possible conflict of interest and lack of uniformity that may result if States become certifying bodies. One general comment recommended that FDA monitor ACR, rather than facilities.

Comments about the States as certifiers go beyond the scope of this document and will be addressed in future proposed regulations covering States as certifying agents. However, the agency notes that the MQSA expressly provides that States may serve as certifying bodies (42 U.S.C. 263b(q)). Preparations are under way to draft proposed regulations that would govern State agencies that wish to become certifying bodies. Just as these final regulations establish standards and procedures for accreditation bodies, including State agencies that serve in that capacity, provisions regulating States as certifying bodies would establish standards and procedures that States must meet to assume that responsibility. Those standards and procedures would address uniformity of standards and include conflict of interest provisions, as do the regulations governing accreditation bodies.

Members of the public will have full opportunity to comment further on States as certifiers when those regulations are proposed. In response to the comment that urged FDA to monitor ACR rather than facilities, the agency notes that the statute requires FDA to monitor both accreditation bodies and facilities in a variety of ways.

(Comment 95). One comment wanted FDA to promote multiple accreditation bodies because of concerns that States approved as accreditation bodies will have overly stringent requirements.

States approved as accreditation bodies are required to accredit facilities under the MQSA in accordance with standards that are substantially the same as those applied by all approved accreditation bodies. However, the MQSA does not prohibit State regulations from being more rigorous than those of FDA. Although more stringent State requirements cannot be used to deny accreditation under the MQSA, facilities may be required by a State to meet such additional requirements in order to practice mammography in that State.

2. The Clinical and Phantom Image Review Process (§ 900.3(b)(3)(iii)(A) and (B))

These provisions require the prospective accreditation body to provide information that describes its clinical and phantom image review process in its application to FDA.

(Comment 96). One comment requested that this information also be provided to all mammography facilities, stating that it would result in improved overall image quality and would assist facilities denied accreditation to prepare for appeals hearings.

FDA understands that facilities may believe they could prepare better for accreditation review if they had details relating to the procedures the accreditation bodies would be applying during clinical and phantom image review. However, FDA also recognizes that disclosure of the details of such procedures may undermine the integrity of the review process under certain circumstances. FDA concludes that this is a matter for accreditation body policy rather than regulations. The actual clinical attributes reviewed during accreditation are described in the final regulations.

3. Policies and Procedures (§ 900.3(b)(3)(iii)(J))

This provision requires prospective accreditation bodies to provide FDA with information describing policies and procedures that will ensure timely processing of facility applications for accreditation.

(Comment 97). One comment on this section requested FDA to require accreditation bodies to respond to requests for information or to written communications expressing concerns from facility personnel or other interested parties about the accreditation process. Another comment suggested including a review of the consistency of the accreditation body's responses to facility and industry inquiries as part of the annual evaluation of the accreditation body by FDA.

FDA agrees that timely processing of facility accreditation applications is important to meet statutory certification deadlines and that good communication between accreditation bodies and facilities can improve such timeliness. However, FDA disagrees that specific prescriptive regulations are needed concerning communications between the accreditation body and facilities.

4. Education and Experience Criteria (§ 900.3(b)(3)(iv))

(Comment 98). One comment stated that this subparagraph, requiring that prospective accreditation bodies provide information describing education and experience criteria for its staff, fails to specify minimum acceptable values for these criteria. It also asked for clarification of ''professional staff.''

By professional staff, FDA means those persons evaluating and making decisions on accreditation applications. FDA has established minimum requirements for the clinical image reviewers under § 900.4(c)(5) and for phantom image reviewers under § 900.4(d)(5), but has not issued minimum requirements for other accreditation body staff in order to maintain flexibility for accreditation bodies and to be able to consider alternatives on a case by case basis. FDA's experience under the interim regulations is that every professional member of an accreditation body staff is qualified to perform his or her assigned functions.

5. Resources (§ 900.3(b)(3)(vi))

This provision requires prospective accreditation bodies to provide information in their application to aid FDA in determining if the body has adequate resources to carry out its responsibilities.

(Comment 99). One comment asked what constitutes adequate funding, what specific additional resources are required and in what amount, and how FDA expects to evaluate the adequacy of an application if no minimum requirements exist for such resources.

Funding and other resource needs, e.g., personnel and data systems, are a function of the variable conditions under which accreditation bodies may operate and the populations they may serve.

FDA could not establish rigid funding or staffing requirements to apply to every accreditation body applicant. As issued, the regulations provide FDA with authority to obtain information to evaluate the individual circumstances of each applicant.

6. Other Information (§ 900.3(b)(3)(xiii))

This subparagraph requires a prospective accreditation body to provide any information required by FDA beyond that specifically listed in § 900.3(b)(3).

(Comment 100). One comment described this requirement as exceedingly vague and recommended it be deleted.

FDA must reject this suggestion because the requirements that accreditation bodies provide FDA with additional information is in the statute itself (42 U.S.C. 263b(e)(1)(vii)). The drafters of the MQSA recognized that it would be impossible to foresee in advance when circumstances might create the need for additional information.

FDA has added one provision to § 900.3(b)(3) to obtain information from prospective accreditation bodies about procedures and policies they would implement to protect confidential information. This requirement is at § 900.3(b)(3)(ix) and its addition has caused the subsequent sections to be renumbered.

7. Term of Approval (§ 900.3(g))

(Comment 101). A small number of comments, both pro and con, were received concerning the accreditation body's term of approval, proposed by FDA to be 5 years. Some, including members of NMQAAC, stated that this term was too short, particularly in light of FDA's annual accreditation body evaluation. These comments also expressed concern about the amount of paperwork required for renewal.

In response to these concerns, FDA has increased the renewal period in the final regulation to 7 years. Because FDA shares the concern about the amount of paperwork required for renewal of accreditation body approval, the agency plans to limit the data required to be submitted to only that information necessary to justify renewal. FDA will hold discussions with each accreditation body prior to renewal to identify the information that will be required. Such information may include, but is not limited to, information and data pertaining to the accreditation body's program not previously submitted to FDA and all proposed changes to the accreditation body's program or standards.

*F. Standards for Accreditation Bodies (§ 900.4)*

Accreditation bodies are responsible for the initial screening of mammography facilities. They are to ensure that the facilities they accredit meet the quality standards established by FDA, both initially and on an ongoing basis. They also have unique responsibility for conducting reviews of clinical images from the facilities to determine if the images meet the image quality standards established by the accreditation body with FDA approval. This section of the regulations outlines the requirements that FDA-approved accreditation bodies must meet in carrying out these responsibilities.

1. General Comments on the Standards for Accreditation

(Comment 102). One comment generally supported this section as written, while a second applauded the regulations for not requiring specific measures of interpretive performance. Other comments encouraged FDA to add additional requirements and responsibilities for accreditation bodies, but did not identify what these should be. One comment stated that the proposed rules for accreditation bodies suffered from a lack of either design or performance-based criteria, but failed to suggest any design or performance-based criteria that should be applied.

FDA believes that the final regulations governing accreditation bodies are sufficiently detailed without being overly prescriptive. Although particular performance-based requirements were not identified by these comments, FDA notes that some performance data on accreditation body activities are available and are used by FDA in its annual evaluation of each accreditation body.

(Comment 103). One comment recommended that each accreditation body be required to demonstrate expertise in recordkeeping and epidemiology.

FDA believes that its review of the accreditation body's application will provide sufficient information to establish that the accreditation body has recordkeeping capability. Although accreditation bodies may employ epidemiologists, nothing in the MQSA suggests that FDA should make this a requirement.

(Comment 104). One comment stated that excessive requirements for accreditation bodies will destroy the basic concept behind the idea for accreditation bodies, i.e., significant involvement of the public and professional sector. The comment warned that detailed rules could reduce the opportunity for creative approaches and innovative development of new QC tests and procedures. A second comment stated that FDA should not hinder the accreditation bodies from performing as independent entities.

FDA shares concerns that overly detailed requirements may limit professional involvement and useful innovation. Although it may appear that the final regulations include many new requirements for accreditation bodies, to a large extent the provisions reflect procedures and criteria that the current accreditation bodies already are following under the interim regulations. In fact, many were first devised by the accreditation bodies themselves and are examples of accreditation body innovation, e.g., development, submission, evaluation, and monitoring completion of corrective action plans by facilities found to have problems producing quality mammograms. FDA has taken great care to delete or amend requirements that might limit creative approaches and innovation. Because the comment does not identify specific rules in the proposal that might cause such problems, the agency cannot respond further.

In response to the second comment, the agency notes that the MQSA requires FDA to establish standards for, and to approve accreditation bodies. Entities that apply to become accreditation bodies must comply with those standards. FDA does not believe that compliance with those standards will diminish the ability and obligation of accreditation bodies to make independent professional judgments. Those judgments, however, must be consistent with statutory obligations to ensure that facilities comply with the Federal standards and work with FDA to improve the practice of mammography. Accreditation bodies are free to encourage innovation, conduct research, develop new standards, and apply for appropriate variances when a particular practice or procedure presents an opportunity to enhance mammography quality.

2. Code of Conduct and General Responsibilities (§ 900.4(a))

These provisions were intended to describe the responsibilities of the accreditation body when there is a possibility that mammography practice at an accredited facility poses a risk to human health. As proposed, those sections set forth particular actions an accreditation body would be required to take in those circumstances.

a. *Image quality (§ 900.4(a)(1) and (a)(2))*

(Comment 105). One comment stated that the accreditation body should have the discretion to determine the appropriate review for a given circumstance and the option to initiate other actions FDA had not described in the proposal (e.g., random film checks followed by a site visit, if necessary). Three other comments recommended deletion of these paragraphs and the substitution of guidance documents that would give accreditation bodies more flexibility.

FDA generally agrees with these comments and has eliminated most of the detailed provisions of these paragraphs (including all of proposed paragraph § 900.4(a)(2)). The final provisions establish that the accreditation body has a responsibility to review clinical images or other

aspects of a facility's practice any time it obtains or receives information that suggests a facility is not in compliance with the MQSA standards, or upon request from FDA. The accreditation body also has responsibility to require and monitor corrective actions or to suspend or revoke a facility's accreditation if the accreditation body's, or FDA's, review confirms that a problem exists. These responsibilities are integral to the role accreditation bodies play under the MQSA to assist the government in establishing and monitoring quality standards for mammography. Nothing in the final regulations precludes an accreditation body from initiating investigations on its own.

b. *Equipment or practices that pose a serious risk (§ 900.4(a)(2))*

(Comment 106). Six comments recommended changing the requirement that an accreditation body inform FDA on becoming aware of situations of potentially serious risk to the public health from ''within 5 business days'' to ''the next business day.''

FDA agrees with concerns raised by these comments and has changed the requirement to ''as soon as possible but in no case later than 2 business days.'' The standard that triggers such responses has been amended to those that ''pose a serious risk to human health'' in order to ensure that FDA is informed of all problems that may require immediate followup.

c. *Conflict of interest (§ 900.4(a)(4))*

The goal of this provision was to ensure that actions of the accreditation body's clinical or phantom image reviewers were not affected by any conflict of interest, and to ensure that accreditation bodies avoid the appearance of such conflicts in order to establish and maintain confidence in the accreditation process.

(Comment 107). Four comments recommended expanding clinical image reviewer conflict of interest concerns to include the individual's family, corporations, partnerships, and associations.

FDA disagrees with these comments. The comments provided no arguments to support this recommendation and no evidence to suggest that the present conflict of interest provision is inadequate. In addition, FDA believes limitations suggested by the comment would eliminate some highly qualified clinical image reviewers from eligibility without commensurate benefit to the system. The agency notes that, if similar conflict of interest provisions had been applied to membership on NMQAAC, many of the members that played a major role in developing final regulations would not have been eligible to serve on the committee.

(Comment 108). One comment recommended expanding the conflict of interest provision to specify that clinical and phantom image reviewers must not review images from facilities within the State in which they reside. A second comment also expressed concern about clinical image reviewers evaluating images from their own States or geographically limited areas. The comment proposed that FDA require ''blind'' readings of all images by reviewers and prohibit review if there is potential conflict of interest.

FDA disagrees with the suggestion that reviewers should be barred from reviewing images from the State in which the reviewer resides. Such a requirement would effectively preclude State accreditation bodies from having independent clinical image review programs. All present State accreditation bodies with independent clinical image review programs require and take measures to ensure blind reading to preclude bias, and FDA expects that any future State or national accreditation bodies will have similar safeguards as part of their QC, clinical image review, and conflict of interest standards.

(Comment 109). One comment recommended that ACR and any other professional organizations acting as accreditation bodies randomly select clinical image reviewers and phantom image reviewers from a pool to reduce the possibility of reviewer bias.

FDA agrees in principle that accreditation body reviews should not be biased, but finds no compelling reason to require use of pools and random selection. Under the MQSA, FDA has issued minimum requirements for all interpreting physicians and these requirements apply to any clinical image reviewer employed by an accreditation body. In addition, with these provisions, FDA is requiring each accreditation body to establish and implement procedures to train and evaluate its reviewers and to avoid conflict of interest. Within this framework, FDA concludes that the assignment of clinical image reviewers for any applicant facility is best left to the accreditation body.

d. *Equipment performance and design characteristics (§ 900.4(a)(5))*

These provisions are intended to prevent conflict of interest situations that could arise if the use of specific products were required by an accreditation body as a condition of accreditation.

(Comment 110). One comment stated that there may be an appearance of a conflict of interest by accreditation bodies in these situations and that special care must be taken with respect to the promotion of any product. The comment expressed the conclusion that the possibility of conflict is so great that it should never be acceptable for an accreditation body to require use of a particular product. A related comment stated that the accreditation bodies should not be able to require use of their own products by facilities they accredit. Over 15 additional comments opposed allowing the accreditation bodies to require the use of their products as a condition of accreditation or otherwise opposed commercial activities that would create a conflict of interest.

FDA understands the concerns expressed in these comments and notes that, in general, the regulation has been written to preclude accreditation bodies from requiring use of any specific brand or product. However, the agency believes exceptional situations may develop that warrant use of a particular product because of the public health benefits the product provides. The final regulation, therefore, gives FDA the flexibility to permit accreditation bodies to require the use of a specific commercial product when the agency has determined that such use is in the best interest of the public health.

(Comment 111). A few stated that conflict of interest requirements should not be an impediment to development of new technologies and services, nor be used by other entities to ''harass'' ACR and improperly influence FDA.

FDA agrees that conflict of interest provisions should not impede the development of new technologies, but also believes that it would undermine the integrity of the accreditation process if accreditation bodies could require facilities to use products the accreditation body develops as a condition of accreditation. FDA believes that the final regulations strike the proper balance between these competing interests.

(Comment 112). Over 150 comments on identical printed forms stated that FDA should prohibit conflicts of interest by accreditation bodies and should adopt the conflict of interest provision suggested by a trade association and included in the preamble to the final regulations (61 FR 14487).

FDA agrees that conflicts of interest by accreditation bodies stemming from accreditation body requirements to use specific products or services should be prohibited. However, none of these 150 comments offered arguments to support adopting the suggested provision or to explain why the agency's proposal was inadequate. FDA's experience under the

interim regulations demonstrates that potential conflicts can be addressed satisfactorily by the provisions of § 900.4(a)(6). The suggested conflict provision would effectively preclude development of products and services by an accreditation body. FDA believes that because accreditation bodies possess particular experience and expertise, such products and services have the potential to enhance practice or otherwise be beneficial to public health. For these reasons, FDA has concluded that it is unnecessary and would be inadvisable to adopt the suggested conflict provision.

(Comment 113). One comment stated that only FDA, as opposed to accreditation bodies or other entities, should be able to require the use of particular mammography related products and, if FDA does so, the use of such products should be required of all facilities.

FDA agrees with this comment as a general rule. However, FDA may approve the imposition of such a requirement by an accreditation body if the agency determines that it is in the best interest of public health to do so. Such an accreditation requirement would only apply to facilities accredited by the accreditation body that requested the approval unless FDA determined that adoption of the same requirement by all accreditation bodies was in the best interest of quality mammography.

(Comment 114). One comment requested clarification on the use of the word ''product,'' apparently asking whether the word was intended to apply to a specific item or a general category of products.

FDA believes that the word ''product'' is commonly understood. The conflict of interest provisions prohibiting an accreditation body from requiring a product to be used can apply to several product categories or to specific brands or products, depending on the circumstances.

(Comment 115). Finally, one comment made several suggestions related to these provisions. The comment contained the recommendations that FDA should require of accreditation bodies that: (1) Their accreditation and onsite inspections be managed by different departments; (2) their clinical image reviewers not review images from facilities in their home State to avoid a range of potential conflicts of interest; (3) reciprocity agreements between adjacent States be precluded; and (4) they meet at least the minimum standards of operation of the ACR program.

FDA believes that the internal division of responsibilities within accreditation bodies is not appropriate for regulation; many professional and government agencies have dual responsibilities for accreditation and inspection and are able to carry out those responsibilities fairly and effectively without necessarily using different departments. It was noted previously that the second suggestion was not accepted by FDA because it would effectively preclude State accreditation bodies from having independent clinical review programs. Because the third suggestion does not identify or otherwise describe the reciprocity agreements intended to be prohibited, the agency cannot respond. In answer to the last suggestion, FDA notes that all accreditation bodies are required to meet the final regulations governing accreditation bodies in order to become approved and maintain their accreditation authority. FDA will not approve any accreditation body that does not have standards of operation that ensure the accreditation body can meet its obligations under the MQSA. Nothing in the MQSA precludes ACR or any other accreditation body from having additional standards for aspects of mammography that are not within the scope of the MQSA. Nor does the MQSA impinge on a State's ability to enforce its own standards under State authority if those standards are at least as stringent as the MQSA's.

e. *Denial of accreditation to a facility (§ 900.4(a)(7))*

This paragraph was intended to ensure that no State accreditation body could bar facilities in that State from being accredited under the MQSA by any other FDA-approved accreditation body.

(Comment 116). Several comments raised questions that made it evident that this section was unclear as proposed. Comments asked whether a State accreditation body could require or restrict facilities within that State to accreditation by the State accreditation body. Other comments asked whether facilities could have more than one accreditation. This section has been rewritten so that the answers to both questions should be unambiguous.

As revised, the provision clearly states that no accreditation body can require a facility to be accredited by that accreditation body if more than one accreditation body is available. Nor can an accreditation body preclude a facility from being accredited by any other available accreditation body. Consequently, nothing in the final regulations prevents a facility from having more than one accreditation. However, FDA will issue only one certificate, usually based on the initial accreditation.

The geographic scope of authority for an accreditation body will be established through the accreditation body approval process. A State certainly could determine, as all current State accreditation bodies have, to restrict accreditation body activities to facilities within the State. A non-State accreditation body similarly could request to be approved to accredit in a limited geographic area. It would be up to the applicant to initially identify, based on its circumstances and resources, the area it intends to serve. In addition, FDA could restrict the scope of an accreditation body's authority to a geographical area that is smaller than that desired by the accreditation body if, for example, the agency had doubts about the ability of the accreditation body to provide adequate service in the desired area.

(Comment 117). One comment asserted that a State government cannot be restricted at any time from requiring its own accreditation guidelines to be met by facilities in that State.

FDA agrees that States may require facilities to meet standards under State law that are at least as stringent as those under the MQSA. However, such standards may not be required as a condition for accreditation under the MQSA.

One comment expressed the view that this provision was unnecessary because a facility accredited by a State agency would not voluntarily seek accreditation elsewhere. FDA disagrees with this comment. A small number of facilities have sought and received dual accreditation. In addition, the main point of the provision is to ensure that facilities are able to seek initial and exclusive accreditation under the MQSA from another accreditation body, even if the State acts as an accreditation body in their geographic area.

f. *Changes to standards (§ 900.4(a)(8))*

(Comment 118). FDA received two comments on this section, which requires an accreditation body to obtain FDA permission prior to changing any standards previously accepted by the agency. Both comments were generally supportive of the provision. One comment suggested verifying whether current technology is capable of meeting the requirements for any change in standards before the change is made. This will serve to minimize costs for both facilities and industry.

FDA agrees with this comment and routinely considers the adequacy of current technology during development of new standards or evaluation of

standards proposed by the accreditation bodies.

(Comment 119). One comment further stated that any proposed change to any standard by an accreditation body should be supported by scientific data and that FDA should seek industry input before authorizing the change. FDA agrees that changes in standards, and especially technical standards, benefit from the application of scientific data, where possible. The agency further agrees that industry input is often useful. However, FDA believes that, in many circumstances, the information already available to the agency is sufficient for a decision and that additional scientific data and outside comment will not be necessary. Therefore, FDA did not make this a regulatory requirement.

g. *Confidential information (§ 900.4(a)(9))*

This paragraph requires the accreditation bodies to establish procedures to protect confidential information.

(Comment 120). Ten comments asked how FDA will ensure that confidentiality will be maintained.

The intent of this provision is to guarantee that each accreditation body has in place procedures, programs, and systems that train employees to guard against unauthorized disclosure of information. Federal regulations, State laws, and contractual obligations will all play a part in determining an accreditation body's responsibility in any particular situation. In general, however, if FDA shares nonpublic information with an accreditation body about a particular facility, the record containing that information is an agency record under the control of FDA and the accreditation body would not be authorized to disclose that information without the permission of the agency. If an accreditation body, in violation of the final regulations, were to improperly use or disclose information received from a facility for purposes of accreditation, FDA believes the facility would have a private right of action against the accreditation body under the laws of most States. In addition, unauthorized disclosures of information, whether received from FDA or the facility, would be a basis for FDA to withdraw an accreditation body's approval. Nothing in these regulations, however, is intended to preclude or hinder the exchange of information between FDA and accreditation bodies when that information is required to be shared in order for the agency and the accreditation body to carry out functions under the statute.

(Comment 121). Three comments recommended allowing accreditation bodies to use and disclose information gathered during the accreditation process, if the identification of an individual, facility, or group is not compromised. Each comment cited the Freedom of Information Act (FOIA). A similar comment found this regulation to be overly restrictive, and stated that the regulation should allow use of the data for research purposes, ''so long as the released data involves only pooled information that does not allow identification of an individual, facility, or group.''

FDA generally agrees with these comments. Disclosure of aggregate information that does not reveal, directly or indirectly, the identity of particular facilities or individuals, is consistent with the FDA's regulations implementing the FOIA. However, in the event of ambiguity, accreditation bodies would consult with FDA and obtain clearance before making such disclosures. FDA does not believe data obtained from facilities for accreditation purposes should be used for purposes that have no relationship to accreditation body processes or standards, unless the accreditation body obtains the consent of the facility. This would not impede an accreditation body from using data to review and improve its internal processes, to educate personnel to improve accreditation body efficiency and performance, or to publicly discuss results of the processes using aggregate data.

(Comment 122). One comment noted that all data collected by or emanating from State agencies may be releasable under some State laws, and that nonpublic information is not necessary for accreditation. The comment also sought clarification about what would be deemed nonpublic information. A second comment stated that, in Arkansas, all information received by a publicly funded agency for accreditation review is releasable under that State's Freedom of Information (FOI) laws. A third comment, which also requested clarification on public versus nonpublic information, suggested that public information be limited to name, address, phone, and accreditation status. The comment noted that there have been complaints from radiologists about the use of information, including concerns about selling the MQSA certified facility address list.

FDA recognizes that people have varying ideas about what constitutes nonpublic information. Any information in the possession of FDA that is prohibited from disclosure under various statutes FDA enforces or that is exempt from mandatory disclosure under the FOIA is considered nonpublic information by the agency. Examples of such nonpublic information include data about the volume of business handled by any particular facility, the name or personal identifier of any mammography patient, and internal recommendations for enforcement action. FDA would not make such information public in response to a request for information under the FOIA.

As stated previously, accreditation bodies that obtain nonpublic information from FDA will be required to treat it as an FDA record and protect it accordingly. If an accreditation body obtains similar information from other sources, FDA expects the information will receive similar protection in the vast majority of cases. FDA has had public information regulations in place implementing the FOIA since 1977. During those years, FDA has found that State confidentiality laws are usually consistent with FDA's requirements. Arkansas' FOI law, e.g., which was cited by one comment, has provisions for exceptions to mandatory public disclosure that are similar to the Federal FOIA and FDA's implementing regulations. In situations where the accreditation body believes that State law requires disclosure of information that would be considered confidential if it were part of an FDA record, every effort will be made to consult State authorities and resolve the apparent inconsistencies.

In addition, FDA notes that all the currently approved accreditation bodies have had experience handling sensitive nonpublic information. ACR has done so for many years and, since the beginning of its voluntary MAP in 1987, has handled and processed information very similar to that required under the MQSA. The State accreditation bodies also have broad experience processing and protecting sensitive information because they have had previous responsibility regulating facilities under their own State laws. FDA has no evidence that any accreditation body has improperly disclosed information.

With respect to the comment that complained about the sale of a list of certified facilities, FDA notes that this sale was not by an accreditation body, and that the names and addresses of certified facilities would not, in any case, be nonpublic information. The list is available from NTIS for a nominal charge to cover the cost of reproduction and is also available from the Center for Devices and Radiological Health Internet site.

(Comment 123). Ten comments stated that permission to disclose nonpublic

information should rest with the facility, not FDA.

The final regulations are consistent with these comments. An accreditation body may not disclose to the public any nonpublic information it has obtained from a facility without the permission of that facility. If an accreditation body has obtained information about a facility from FDA or its duly designated representatives, including a State agency with responsibility for monitoring mammography facilities, the accreditation body cannot further disclose that information without the written permission of FDA. Because FDA is obligated to protect nonpublic information, it would not authorize release of information about any facility that was entitled to be protected from disclosure under the Federal law. FDA has added references in the final regulations to information obtained from or provided to State agencies because FDA's experience under the interim regulations demonstrates the necessity for sharing information among accreditation bodies, State authorities, and FDA in order to ensure quality mammography.

3. Facility Standards (§ 900.4(b))

This section outlined the responsibilities accreditation bodies must meet to ensure that facilities they accredit meet the FDA quality standards.

a. *General comments on facility standards*

(Comment 124). Seven comments requested that FDA add an additional provision to state, ''The accreditation body shall review previous inspection reports prior to issuing full accreditation.'' Eight additional comments recommended adding that sentence, plus the additional words, ''to previously accredited facilities'' at the end.

FDA appreciates the concerns of these comments that accreditation bodies have access to complete information about facilities that are applying for accreditation for the first time or to renew their accreditation. FDA disagrees that accreditation bodies should be required to review all prior inspection reports for every application it receives. Such a requirement could raise accreditation costs unnecessarily, and the prior accreditation history that each facility must submit with its accreditation application will provide a summary of significant related information. However, FDA encourages accreditation bodies to request inspection records from FDA whenever the accreditation body believes that such records would aid in review of an accreditation application.

b. *Monitoring facility compliance (§ 900.4(b)(1))*

Under this provision, an accreditation body must require each facility it accredits to meet quality standards that are substantially the same as those required by FDA.

(Comment 125). Six comments recommended using this provision to make the accreditation bodies responsible for reviewing continuing education and other personnel requirements, thereby eliminating verification of these personnel standards from the annual inspections.

FDA notes that the accreditation bodies have the responsibility under the interim regulations to ensure that personnel qualifications are met before they accredit a facility and will continue to have that responsibility under the final regulations. However, the number of personnel noncompliances found during inspections over the last 2 years illustrates the value of an onsite check of these qualifications. As experience with inspection and accreditation activities develop, FDA is working with the accreditation bodies to improve and enhance the role each plays in oversight of facility compliance with quality standards.

(Comment 126). One comment recommended replacing ''substantially the same'' with ''the same'' to ensure clarity.

FDA disagrees with this comment. The MQSA does not contemplate that the standards be identical; the statute uses the phrase ''equal to'' (42 U.S.C. 263b(e)(1)(B)(vi)). Using ''the same'' would unduly restrict accreditation bodies, and effectively preclude relatively minor differences that are necessary or appropriate because of different or changing circumstances among accreditation bodies.

c. *Facility compliance (§ 900.4(b)(2))*

(Comment 127). One comment stated that accreditation bodies should not be required to ensure that a facility correct noncompliances because accreditation bodies have no authority in these matters. Instead, the comment suggested that accreditation bodies be required to refer enforcement matters to FDA or, in the future, to a State certifying entity.

As discussed previously, FDA agrees that enforcement matters are ultimately the responsibility of the agency. This provision has been modified accordingly. As discussed previously (see section III.F.1 of this document), accreditation bodies have responsibility and authority to monitor compliance with standards and to suspend or revoke accreditation of facilities that do not maintain standards.

4. Clinical Image Review (§ 900.4(c))

FDA believes that effective clinical image review is essential for high quality mammograms. A primary purpose of the MQSA is to ensure that all mammography facilities have the benefit of such review and that accreditation bodies are qualified to perform that function. Accordingly, FDA proposed more specific requirements with respect to clinical image review than were established under the interim regulations. The proposed requirements, which were based on advice from NMQAAC and public comments, have been codified without significant changes in the final rule.

The regulations define three separate but related types of clinical image review. They are accreditation and reaccreditation clinical image review, random clinical image review, and additional mammography review. Each serves a different purpose within the framework of the MQSA and the regulations.

Accreditation and reaccreditation clinical image review is performed for each facility once every 3 years. Its purpose is to ensure that each facility is capable of producing and recognizing high quality images of fatty and dense breasts. Section 900.4(c) has been retitled in the final regulations from the general title that had been proposed, ''Clinical image review,'' to ''Clinical image review for accreditation and reaccreditation'' to clarify that the provisions of this section refer specifically to clinical image reviews performed for accreditation and reaccreditation.

In addition to clinical image review performed for routine accreditation and reaccreditation, the MQSA also requires the accreditation body to conduct random clinical image review. This type of review is performed on a selected sample of the accreditation body's facilities and serves three major purposes. Random clinical image review is an indicator of the quality of mammography performed at facilities, a measure of the performance of the accreditation body, and a method to assure the public that facilities continue to produce high quality images during the intervals between reaccreditation reviews. Under the provisions of § 900.4(f)(2), FDA is allowing each accreditation body to develop its own FDA-approved random clinical image review process to include at least 3 percent of its accredited facilities each year. This enables each body to individualize the review to best evaluate its facilities and monitor its own performance. While the accreditation bodies will be evaluating the same

attributes used for accreditation and reaccreditation clinical image review, they will have to adjust their scoring and pass-fail criteria to take into account that, due to the selection process, these studies may not be representative of the best images a facility can produce.

The third type of review is additional mammography review. This review is an evaluation of facilities that FDA has reason to believe may present a serious risk to human health due to compromised mammography quality. The term ''additional clinical image review,'' used in the proposal, was changed to ''additional mammography review'' to indicate that this review of problem facilities is not necessarily limited to an evaluation of clinical images but can involve all aspects of mammography at the facility. The requirements for this type of review are provided in § 900.12(j).

a. *Frequency of clinical image review (§ 900.4(c)(1))*

Section 900.4(c)(1) states that clinical image review for accreditation and reaccreditation shall be performed at least once every 3 years. This is in accordance with the requirements specified by the MQSA.

b. *Attribute requirements (§ 900.4(c)(2))*

Section 900.4(c)(2) lists the eight attributes to be used for evaluating clinical images.

(Comment 128). One comment agreed with the section as proposed, while another comment thought it was too proscriptive and did not allow for changes in technology and assessment. Two other comments stated that the attributes were too vague, while another said that the attributes should be identical to any existing standards and definitions currently in use.

FDA notes that the attributes described in § 900.4(c)(2) were derived from existing standards that have been used successfully for mammographic evaluation for many years. Accreditation bodies are currently using these attributes to evaluate clinical images under the interim regulations. FDA does not believe the use of these attributes will limit the introduction of new technologies because FDA has the flexibility to modify the attributes for new mammographic modalities, if necessary.

(Comment 129). One comment recommended that the contrast, sharpness, and noise attributes should be dropped because all mammograms contain some blurring and noise.

FDA agrees that some degree of blurring and noise occur on all films. However, these attributes should be evaluated to determine if the blurring or noise are of such severity as to obscure anatomical structures.

(Comment 130). Several comments addressed specific attributes. One comment stated that the positioning attribute implies that it is not necessary to get all the breast tissue on the film.

FDA notes that, due to anatomical and mammographic limitations, all breast tissue cannot be imaged on each view. The requirement was specifically written by FDA to take this fact into account.

(Comment 131). Several comments, including one from NMQAAC, urged that the word ''tissue'' be replaced with ''image'' when referring to exposure and that ''processing'' should be added to the list of ''artifacts.''

FDA agrees that ''processing'' should be added to the list of ''artifacts'' and has changed ''tissue exposure'' to ''exposure level'' to be more consistent with existing standards and definitions.

(Comment 132). One comment was unclear as to whether ''noise'' was the same as ''quantum mottle.'' FDA notes that ''quantum mottle'' is a form of ''noise,'' although it is not the only form of ''noise.''

(Comment 133). Several comments opposed the examination identification attribute as being too specific and requiring too much information to be placed in the small flasher space. Two comments supported the description of the attribute as written.

FDA has received a great deal of advice from NMQAAC regarding the importance of examination identification as an attribute of quality mammography and believes that the present requirement is in the best interest of the patient. A facility may satisfy the requirements for examination identification through the use of stick-on labels so that all the information does not have to fit within the flasher space. NMQAAC recommended specifically adding the name and an additional identifier to patient identification. FDA agrees with this suggestion and has modified this section accordingly.

(Comment 134). One comment stated that technical factors such as kVp, milliamperes (mA's), and amount of compression should be required on all films because this information would aid in evaluating problems. It noted that ACR recommends recording these technical factors.

FDA believes that facilities should have the option of recording this information if they believe it beneficial for their practice. Because many facilities have indicated that having this information on all images is not useful, the agency does not believe it is cost effective to make this a mandatory requirement for all facilities.

(Comment 135). Two comments, and several members of NMQAAC, stated that FDA must ensure that accreditation bodies prevent reviewers from knowing the identity of the facility under review, especially in the case of local reviewers.

FDA agrees that this is an important issue and has discussed it in response to comments on § 900.4(a)(4), which addresses possible conflicts of interest by image reviewers.

(Comment 136). One comment asked if the technologist identification is meant to be unique for a facility, for a particular health corporation, or nationally recognized. The technologist identification requirement is facility-based and any system that enables the facility to determine which technologist performed the examination should be acceptable.

(Comment 137). One comment agreed that mammography unit identification was important for reproducibility, while another asked whether it would be possible to have the unit identification on the patient's question and answer form rather than on the film.

FDA believes that, in cases where there is more than one unit in the facility, the unit identification should be on the film, so that this information may be obtained without referring to other sources.

c. *Scoring clinical images (§ 900.4(c)(3))*

Section 900.4(c)(3) requires the accreditation body to establish a system for scoring clinical images using the attributes in § 900.4(c)(2) and to develop pass-fail criteria for these attributes. It also requires that images be independently reviewed by two or more clinical image reviewers. This section was modified from the proposal to clarify that each attribute shall be individually evaluated.

(Comment 138). One comment warned that perfectly acceptable images can be rejected by the clinical image review process if a pass-fail system is used. The author believed that there should be some form of grading system for the evaluation of the films.

FDA agrees that a grading system should be employed in evaluating the studies. A requirement for such a system was in the proposed regulations. It has been modified in the final regulations to require that acceptable and unacceptable results be established for each of the eight attributes and an overall pass-fail system. This change ensures that each facility has the benefit of an evaluation of each attribute, providing the facility with the

information essential to take appropriate corrective actions when necessary. FDA's experience under the interim regulations indicates that failure by the clinical image review process of what are later judged to be acceptable images is an unusual occurrence. In those rare cases where the facility disputes an accreditation body clinical image review decision, the facility has the option of appealing this adverse decision to the accreditation body and then to FDA.

(Comment 139). One comment said that the specific details of the scoring process should be made public, utilized in an identical manner by all accreditation bodies, be verified, and result in a numerical score for each set of films reviewed. FDA notes that the determinants of high image quality mammography have already been made public by accreditation bodies, professional organizations, and by clinical authors publishing in peer review radiology journals. This information should be incorporated into each facility's quality assurance program and should be used for selecting the studies that are submitted to the accreditation body for clinical image review. FDA believes that the specific details of the accreditation body's scoring procedures should remain confidential to preserve the integrity of the process. However, the details will be reviewed and evaluated by the agency as part of FDA's approval and oversight responsibilities.

d. *Selection of clinical images for review (§ 900.4(c)(4))*

Section 900.4(c)(4) describes the number and types of images that shall be submitted by the facility for accreditation and reaccreditation clinical image review.

(Comment 140). Four comments stated that accreditation and reaccreditation clinical image review should be done on randomly selected images rather than the ''best'' images a facility can produce, arguing that this would give a better indication of the quality of mammography being performed. One comment agreed with § 900.4(c)(4) as proposed, but suggested adding one randomly selected set of images. One comment mistakenly believed that FDA was allowing accreditation bodies to use either random or nonrandom selection of clinical images for accreditation or reaccreditation clinical image review.

FDA has retained the provision that accreditation and reaccreditation clinical image review is to be performed using the ''best'' images a facility can produce. Using this criterion for selection allows the accreditation body to apply its highest standards to the scoring of these images. It also serves as a check on facility personnel to see if they understand what makes a high quality image. Random clinical image review, as required in § 900.4(f), serves a different purpose than accreditation and reaccreditation clinical image review. Although the accreditation body evaluates the same attributes, the scoring standards are more flexible to take into account that these may not be the ''best'' images a facility can produce.

(Comment 141). Two comments stated that clinical image review is extremely valuable, but that more films should be reviewed.

FDA disagrees. Requiring review of additional studies would serve to raise the cost and complexity of the review process without a demonstrable increase in quality. During discussions with NMQAAC, a majority of the committee agreed with FDA's position on this issue.

(Comment 142). Two comments urged FDA to replace the term ''view'' with ''projection.''

FDA discussed this with NMQAAC, who agreed with the agency that ''view'' is the correct term to use in this context.

(Comment 143). Six comments stated that clinical images for accreditation and reaccreditation review should be selected from a specified period of time. Three comments, including a consensus of NMQAAC, stated that both the clinical images and the phantom image should be from the same 30-day period.

FDA did not set timeframes for submission of images in the regulations in order to allow the accreditation bodies to establish these timeframes based on their own circumstances and experience with the review process. The agency has rejected the suggestion that phantom and clinical images be from the same 30-day period because this could create logistical problems if a second set of clinical images had to be submitted.

One comment expressed the author's belief that a national accreditation body should develop materials showing examples of acceptable dense and fat-replaced breast images. FDA encourages accreditation bodies to provide such information and education but does not believe that this is a matter that should be addressed in regulation.

(Comment 144). Several comments, including a consensus of NMQAAC, stated that it is often difficult to find images that are totally normal and suggested that images could be sent from either negative or benign assessment categories.

FDA agrees and has modified § 900.4(c)(4)(iii) accordingly.

(Comment 145). One comment suggested that § 900.4(c)(4)(iv) be revised to allow a facility to submit alternative mammograms only if the facility does not have images interpreted as normal under § 900.4(c))(4)(iii). It stated that no alternatives should be accepted for craniocaudal and mediolateral views required in § 900.4(c)(4)(I) or for dense and fatty breast images required in § 900.4(c)(4)(ii). FDA disagrees and believes that accreditation bodies should be given the flexibility to deal with these situations in an appropriate and individualized manner.

e. *Clinical image reviewers (§ 900.4(c)(5))*

Section 900.4(c)(5) requires the accreditation body to ensure that its clinical image reviewers are interpreting physicians, are trained and evaluated in the clinical image review process, document their findings and the reasons for assigning a particular score to any clinical image, and provide information to the facility for improving image quality.

(Comment 146). Several comments, including some from NMQAAC, stated that criteria for clinical image reviewers should be more detailed and that FDA should specify a minimum training and evaluation curriculum or other performance-based measure. One comment stated that it was essential for all accreditation body clinical image reviewers to meet minimum standards of reliability.

FDA notes that § 900.4(c)(5) establishes the basic requirements for clinical image reviewers and serves as the starting point for the accreditation bodies to develop their own additional requirements. Through its oversight activities, FDA ensures that the different accreditation programs are internally and externally consistent. FDA currently monitors accreditation body policies to achieve consistency in critical areas. The agency has worked and continues to work with the accreditation bodies to enhance existing procedures and establish new programs to monitor inter- and intra-accreditation body consistency for clinical image review.

(Comment 147). Five comments suggested that inspectors be trained to be clinical image reviewers. These comments reasoned that such training would permit a more accurate evaluation of clinical image quality than the current practice of letting facilities pick their best films for accreditation body evaluation. One of the comments contended that image quality would improve overall if a facility knew that

any image could be reviewed during inspections.

The MQSA assigns primary responsibility for clinical image review to accreditation bodies. The agency has established basic standards for clinical image reviewers, including that they be interpreting physicians, and will review and monitor each accreditation body's performance of this critical function. However, FDA believes the actual evaluation of clinical images should remain the role of the accreditation body. At its January 1997 meeting, NMQAAC discussed the issue of using the MQSA inspectors for clinical image review. They concluded, and the agency agrees, that inspectors do not have, nor can reasonably be given, the training and expertise required to perform clinical image review.

f. *Image management (§ 900.4(c)(6))*

Section 900.4(c)(6) requires the accreditation body to establish a tracking system for clinical images to ensure their security and return to the facility within 60 days.

(Comment 148). One comment stated that the requirement to return all clinical images within 60 days was too restrictive, because 60 days would not be adequate if a third review were required. This comment recommended 90 days. Another comment stated that the turnaround time for accreditation body image review was already too long, and that such delays limited a facility's opportunity to submit a second set of improved images within the review time cycle. A third comment stated that films should be returned to facilities in 45 to 60 days.

With respect to this matter, FDA has had to balance the needs of the facility against those of the accreditation body. Using the experience gained under the interim regulations, the agency concludes that the 60-day period is appropriate.

(Comment 149). One comment stated that § 900.4(c)(6)(ii) should clearly state that the accreditation body is obligated to inform only the facility of any abnormalities found on clinical images submitted to the accreditation body which had been interpreted by the facility as negative. The comment explained that this obligation should not extend to informing either patients or referring physicians.

FDA believes it is imperative that patients and referring physicians be notified of any suspicious abnormality detected during the clinical image review process. However, the agency has concluded that only the facility that performed the examination has access to the necessary patient and referring physician information to allow proper notification of the affected individuals. FDA has modified the regulation accordingly.

(Comment 150). One comment stated that proposed § 900.4(c)(6) implied that mammography reports would be sent to the accreditation body with the films. The comment asserted that requiring facilities to submit reports would raise concerns about patient confidentiality and establish an additional and new requirement for facilities.

FDA agrees with this comment and the regulation has been amended to delete the reference to mammography reports.

g. *Unsatisfactory image quality (§ 900.4(c)(7))*

Section 900.4(c)(7) describes the accreditation body's responsibility when it determines that clinical images from a facility that it accredits are unsatisfactory.

(Comment 151). One comment stated that the accreditation body has no direct authority to ''take appropriate action'' if corrective measures to address poor clinical image quality are not implemented by the facility.

Section 900.4(c)(7) has been modified from the proposal to address this comment. As discussed previously, FDA agrees that responsibility for enforcing compliance with the MQSA requirements rests primarily with FDA. Accreditation bodies, however, can and are expected to take action to revoke or suspend the accreditation of facilities that do not comply with standards established by the accreditation body, which include producing high quality clinical images. This section has been changed to state that the accreditation body is responsible for notifying the facility of the nature of the problem and its possible causes. The requirements that have been deleted, to monitor the progress of the facility and to take appropriate action if corrections are not made, are inherent in the accreditation process and have been stated previously in § 900.4(a)(1)(ii).

5. Phantom Image Review (§ 900.4(d))

The review of phantom images is an important part of the evaluation of a facility for accreditation. The production and evaluation of phantom images is also an important part of the medical physicist survey, of the facility inspection, and of the facility's quality assurance program. However, § 900.4(d) covers only the requirements that the accreditation body must meet to ensure that its phantom image reviews are performed accurately, in a timely fashion, and without bias.

a. *General comments on phantom image review*

(Comment 152). Two comments stated that phantom image review by the accreditation body is unnecessary because it is performed twice a year, once by the medical physicists during annual physics surveys and again by inspectors during yearly inspections.

FDA notes that, as with clinical image review, the phantom image review performed during the accreditation process and the reviews performed at other times have different purposes. The words ''for accreditation and reaccreditation'' have been added to the title of § 900.4(d) to clarify the purpose of the phantom image review in this section. During the accreditation process, phantom images are reviewed by the accreditation body to determine if the facility is producing adequate quality images to permit its accreditation or reaccreditation. The phantom image reviews conducted during a medical physicist survey, an inspection, or as part of the facility quality assurance program are intended to provide some assurance that the facility continues to produce adequate quality images during the 3-year interval between accreditations. Because of these different objectives, the agency believes that the multiple phantom image evaluations are not redundant.

b. *Phantom image reviewers (§ 900.4(d)(5))*

This paragraph discussed the requirements for and the procedures to be followed by the phantom image reviewers.

(Comment 153). Two comments stated that FDA did not provide any specific qualifications and training requirements for the accreditation body phantom image reviewers in the proposed rule. One comment wanted further clarification of these qualifications and the other expressed concern that accreditation bodies may have widely different criteria for phantom image reviewers. A few comments recommended that only medical physicists be considered qualified for phantom image review, but another comment expressly opposed that limitation. Six comments supported § 900.4(d)(5)(I) as written.

FDA has stated in § 900.4(d)(5)(I) that the accreditation bodies must ensure that their phantom image reviewers meet the requirements specified in § 900.12(a)(3) for medical physicists or alternative requirements established by the accreditation bodies and approved by FDA in accordance with § 900.3(d). The agency believes that this provides sufficient guidance to accreditation bodies with respect to qualifications and training requirements, while permitting flexibility to accommodate different

circumstances among the accreditation bodies.

FDA does not agree with the comments that only medical physicists should be allowed to perform phantom image review, although any medical physicist who met either the requirements in § 900.12(a)(3) or FDA-approved alternative requirements could serve in this capacity. The key criteria are that the individuals doing the phantom image review be adequately trained in the review process and have sufficient educational background to understand the concepts involved. The ability to carry out the full range of the responsibilities of the medical physicists under the MQSA is not required. The agency believes, therefore, with proper training and experience, individuals other than medical physicists can become qualified to evaluate phantom images.

All phantom image reviewers, whether or not they are medical physicists, must comply with the additional requirements, established by FDA in § 900.4(d)(5)(ii) and (iii), to be trained in the review process, to document scoring, and to provide feedback to facilities on improvement measures. If the accreditation bodies develop their own alternative or additional requirements for phantom image reviewers, FDA will ensure consistency among the accreditation bodies through its oversight program.

(Comment 154). Eight comments wanted the agency to require phantom image review by at least two reviewers. One comment stated that all facilities should use the same phantom and the same scoring procedure.

The agency has no evidence to suggest that double reviews are necessary for adequate evaluation and did not make this a regulatory requirement. However, FDA notes that it is currently the common practice of all accreditation bodies to have all failed phantom images evaluated by a second reviewer.

FDA disagrees with the comment regarding the same phantom and scoring procedures for all facilities. The agency wants to refrain from specifying either a phantom type or scoring methodology in order not to inhibit future advancements in phantom evaluation procedures. In addition, experience has shown that phantom type and scoring methodology is generally consistent from facility to facility even without a regulatory requirement. FDA will continue to monitor the situation and will ensure that any different phantoms or scoring methodology that may be in use will not compromise the minimum standards currently approved.

(Comment 155). Two comments on this provision expressed concerns about possible conflicts of interest for reviewers. FDA has addressed this issue in § 900.4(a)(4), which was discussed previously.

c. *Image management (§ 900.4(d)(6))*

As proposed, this paragraph required the return of the phantom image to the facility that produced it.

(Comment 156). Three comments stated that returning phantom images increases costs without benefit. Another stated that retaining the images would allow the accreditation body to compare past and current images to assess possible changes in a facility's QC program.

FDA believes that phantom images that result in a failure of accreditation should be returned to the facility in order to illustrate the accreditation body's assessment of the nature of the problem and its possible causes. Such images can be a valuable learning tool for the facility as it seeks to correct its problems. To minimize costs, however, FDA has revised this paragraph to require the accreditation body to return only those images that cause a failure.

d. *Notification measures for unsatisfactory image quality (§ 900.4(d)(7))*

As proposed, this paragraph described a variety of actions that the accreditation body should take if it finds a facility's phantom image is of insufficient quality to permit accreditation of the facility. The provision has been revised, as has the parallel provision for clinical image review discussed above, to focus on the accreditation body's obligation to notify the facility of the nature of the problem identified and of possible solutions.

(Comment 157). Six comments supported § 900.4(d)(7) as proposed. The comments stated that this requirement provides assistance to the facility and promotes timely correction of problems. Two comments expressed concern that the accreditation bodies could ''close'' a facility on the basis of inadequate quality of phantom images even if the facility had been producing high quality clinical films. The comments explained that this could happen because of the subjective nature of phantom image review and the fact that problematic phantom images are unavoidable, in spite of adequate care.

Because § 900.4(d)(7) requires the accreditation body to notify the facility of the nature of the problem and its possible causes, FDA does not believe the review process will prevent accreditation of a facility that is able and willing to devote resources to improvements in this area. It is the policy of the approved accreditation bodies to offer facilities at least two chances to improve the quality of failed images to the satisfactory level. If the facility uses the information provided by the accreditation body on the possible causes of the problem to guide corrective actions, the agency believes that a facility producing high quality work, as the comments described, should be able to achieve the minimum phantom image quality required by the accreditation body.

(Comment 158). One comment stated that the accreditation body has no direct authority to ''take appropriate action'' if corrective measures are not implemented.

As discussed previously in connection with clinical image review, nothing in the proposed provision would require the accreditation body to act beyond its authority, which includes a responsibility to deny, suspend, or revoke accreditation of facilities that do not achieve the accreditation body's standards. However, the agency has reworded the provision to focus on its primary purpose, which is to ensure that facilities who fail the phantom image review are informed of the causes.

6. Reports of Mammography Equipment Evaluations, Surveys, and QC (§ 900.4(e))

This paragraph describes the reports on the evaluations of their equipment that the accreditation body must require from each facility, the reporting schedule, and the responsibility of the accreditation body to review the reports and to use them in accreditation decisions.

(Comment 159). Several comments expressed varying viewpoints on the need for submission of this information and who should evaluate it. One comment stated that it is redundant for facilities to have to submit information about equipment to the accreditation body because each facility is inspected annually, and also may receive an onsite visit from an accreditation body. This would result in three reviews annually, which would be unnecessary and burdensome to both the facility and the accreditation body. Three other comments also stated the position that the accreditation body should be the sole evaluator of the annual physicist survey. One of the three also contended that the inspector, unless a qualified mammography medical physicist, is not qualified to review these reports. This comment suggested that the inspection review be eliminated and that the accreditation body be required to send a statement to FDA confirming that the report was received and reviewed.

On the other hand, one comment urged that both the accreditation body and the inspector continue to review the physicist survey reports. Another comment stated that, if duplicate review is not deemed cost effective, then the inspector should review the survey rather than the accreditation body. These two comments agreed that it is imperative that the facilities both read the report and correct any deficiencies that could lead to noncompliance or degradation of images, but expressed a concern that facilities would not do so unless both the accreditation body and the inspector required such actions. A third comment agreed that the inspector should not just accept the accreditation body's review of the facility survey. Valuable information would be lost if the inspector does not review the survey.

FDA believes that having both the accreditation body and the inspector review the physicist's report is consistent with the MQSA's reliance on review by different entities and is a benefit to the public health, especially during these early years of the MQSA program. The two checks are different in nature. The accreditation bodies make a complete assessment of such surveys as they are reported annually. Inspectors, on the other hand, do not evaluate the surveys the same way. Instead, inspectors check for completeness and to determine if the facility has implemented necessary corrections identified in the survey. Typically, the submission of surveys to the accreditation bodies and the occurrence of inspections are not coincident. Having the inspectors do an independent check may draw attention sooner to an incomplete survey or a problem found by the survey that has not yet been corrected.

(Comment 160). One comment asked how five facilities became accredited without physicist reports.

FDA and the accreditation bodies are unaware of any facilities that have been accredited without physicist reports. Because the facilities for which such accreditation was alleged were not identified in the comment, it is not possible to respond further.

(Comment 161). Nine comments argued, that as proposed, § 900.4(e)(2)(i) would lead to facilities changing from a 12-month cycle to a 14-month cycle for the medical physicist survey.

FDA agrees with these comments and the section has been changed accordingly.

7. Onsite Visits to Facilities and Random Clinical Image Reviews (§ 900.4(f))

The MQSA requires that accreditation bodies make a ''sufficient number'' of onsite visits to the facilities they accredit ''to allow a reasonable estimate of the performance'' of the body (42 U.S.C. 263b(e)(4)(A)). The statute also requires the accreditation body to conduct random reviews of clinical images from the facilities it accredits, in addition to the clinical image reviews required for accreditation (42 U.S.C. 263b(e)(1)(B)). Section 900.4(f) implements these requirements.

a. *General comments on onsite visits*

(Comment 162). One comment questioned the cost-effectiveness of requiring accreditation bodies to prepare three copies of a summary report describing all facility assessments conducted during that year. The comment asserted that FDA could review this information during the annual oversight inspection of the accreditation body.

Under the statute, FDA is required to evaluate the performance of each accreditation body. The summary of onsite visits provides valuable information on which to base such evaluations. FDA, therefore, retained the requirement that three copies of the summary be included in the accreditation body's annual report to FDA. Multiple copies will allow simultaneous review by multiple reviewers and, in the event that some of the materials are difficult to reproduce, will help ensure uniformity and readability of the materials.

b. *Onsite visits (§ 900.4(f)(1))*

(Comment 163). Three comments agreed with the need for onsite visits, while two comments stated that the visits were unnecessary. Two comments recommended that the onsite visit be combined with the annual inspection, while two other comments stated that the onsite visit should not be construed as a substitute for, or be conducted during, the annual inspection. One comment stated that the onsite visit process does not serve as a check of the accreditation body's quality assurance process.

FDA reiterates that the requirement for onsite visits by the accreditation bodies is established by the statute (42 U.S.C. 263b(e)(4)). The purpose of such visits is to provide a mechanism by which accreditation bodies can ensure facility compliance with quality standards and monitor their own performance of accreditation functions. The accreditation body will be able to compare the consistency of results from visits to information obtained through other accreditation body functions. These onsite visits by the accreditation bodies are different from and are intended to be complementary to the annual inspection of every certified facility performed by FDA or State inspectors. Combining the two evaluations into one review would likely undermine the effectiveness of both visits and inspections. This issue was discussed with NMQAAC and the agency's position was supported by a consensus of the committee.

(Comment 164). One comment recommended a prior notice of 5 days for onsite visits so as not to disrupt patient care. FDA believes that accreditation bodies will need flexibility in scheduling onsite visits. In some cases, particularly if an accreditation body has serious concerns about a facility's ability to meet quality standards, significant advance notice would not be appropriate. In general, for facilities selected randomly for onsite visits, FDA encourages accreditation bodies to work with facilities to schedule visits that minimize patient inconvenience and disruption to facility operations. This has been the general practice of all accreditation bodies.

c. *Sample size (§ 900.4(f)(1)(I))*

Section 900.4(f)(1)(I) requires accreditation bodies to select some facilities for onsite visits on a random basis and select other facilities based on specific reasons for concern about those facilities, such as a previous history of noncompliance with quality standards. In general, each accreditation body will have to visit annually at least 5 percent of the facilities it accredits, up to a maximum of 50 facilities, but no less than 5. The number could exceed 50 if many facilities need to be visited because of previously identified concerns.

(Comment 165). Two comments agreed with § 900.4(f)(1)(I) as proposed. However, 14 comments recommended that the maximum of 50 facilities be raised to a higher number. Reasons given for the increase included a belief that 50 is not statistically significant for a large accreditation body. Two comments wanted the number raised because they had ''seen too many certified facilities with questionable compliance.'' One comment stated that a national accreditation body should visit at least one facility from each State or region.

The agency disagrees with raising the number of onsite visits. FDA has discussed with NMQAAC and the accreditation bodies the issue of the number of onsite visits that an accreditation body can reasonably perform. There was general agreement among NMQAAC and the accreditation bodies that the regulation should not be changed. The agency has had to balance

the benefits of accreditation body onsite visits against its monetary cost. Requiring more than 5 percent or 50 facilities could significantly increase the cost of accreditation and potentially reduce the number of accredited facilities and access to mammography without commensurate benefit.

d. *Visit plan (§ 900.4(f)(1)(ii))*

Section 900.4(f)(1)(ii) establishes baseline standards for the conduct and content of the onsite visits.

(Comment 166). Four comments, including a consensus of NMQAAC, stated that the composition and qualifications of onsite visit teams should be specified. One of the comments recommended that the team be comprised of a qualified active clinical image reviewer, a phantom image reviewer, and an accreditation body staff member.

The agency believes that the accreditation body is in the best position to define the onsite visit team. This gives the accreditation body the flexibility to tailor the team to the specific needs of the facility, thereby reducing costs while maintaining quality.

(Comment 167). One comment believed that the decision to review clinical images and the selection of images should be made at the discretion of the accreditation body at the time of the visit. It stated that, if the facility has proper quality assurance procedures in place, it may not be necessary to review the clinical images. FDA disagrees. The agency believes that clinical image review is one of the most important aspects of the entire MQSA program and should be a part of every accreditation body onsite visit.

(Comment 168). Two comments, including a consensus of NMQAAC, recommended that § 900.4(f)(1)(ii)(D) be amended to require the accreditation body to ''verify the presence'' of the facility's medical outcomes audit system during an onsite visit, rather than ''review'' the system; requiring a review implies that the visit team is evaluating the audit against an agreed upon standard rather than verifying that a system is in place.

FDA agrees and has modified this section accordingly.

e. *Clinical image review for random sample of facilities (§ 900.4(f)(2))*

This paragraph establishes the requirements for the clinical image review for a random sample of facilities.

(Comment 169). Sixteen comments stated that there appears to be a contradiction in the preamble to the proposed regulations because remarks in one section questioned the effectiveness of random clinical image review, but another section stated that random visits for facilities are effective.

FDA believes that the comments are comparing the agency's views of two different processes. The agency believes that random clinical image review is a useful tool in the evaluation of facilities and accreditation bodies. However, the agency stated in the proposal's preamble (61 FR 14890) that random clinical image review would not be an effective use of accreditation body resources if applied to all facilities. Random onsite visits to a limited number of facilities represent a different tool to evaluate facilities and accreditation bodies and, as stated in the preamble to the proposal, are effective in this context.

(Comment 170). One comment stated that the goals of random clinical image review should be clearly determined prior to establishing minimum quality standards.

As previously stated, the purpose of random clinical image review is to serve as an indicator of the quality of mammography performed at facilities, a measure of the performance of the accreditation body, and a method to assure the public that facilities continue to produce high quality images during the intervals between reaccreditation reviews. In this context, FDA believes that it is important that the accreditation bodies be given the flexibility to develop a process for random clinical image review that is best suited to meet their needs and those of their accredited facilities. However, the agency notes that § 900.3(b)(3)(iii) requires a prospective accreditation body, as part of its application, to give FDA a description of its procedures for performing random clinical image review. In addition, the agency will monitor the use of random clinical image review as part of its oversight responsibilities.

Eight comments stated that the sample size for random clinical image review in proposed § 900.4(f)(2)(I) should be increased. Two of the comments recommended that all facilities undergo random clinical image review in each 3-year period. One of these comments stated that this is required by the statute.

FDA addressed this issue in the preamble to the proposed rule and believes its interpretation of the statute is reasonable. FDA's proposal changed the interim rule, which required random clinical image review at every accredited facility, to a requirement that the accreditation body select a sample of facilities for random clinical image review. The change in the sampling requirement was based on FDA's experience under the interim regulations. The agency believes that annual random clinical image review for every facility, in addition to the clinical image reviews required for initial accreditation and reaccreditation, is not an effective use of accreditation body resources. FDA does agree that, after more data are accumulated, the 3 percent sample in the proposal may prove to be too low. The agency, therefore, has revised the provision to state that at least 3 percent of the facilities be sampled annually, to allow the agency more flexibility to modify the sample size if information obtained in the future justifies such a modification.

Section 900.4(f)(2)(ii) has also been revised from the proposal to clarify that reviewers performing random clinical image review shall evaluate the same film attributes used in accreditation and reaccreditation clinical image review.

(Comment 171). One comment stated that randomly selected clinical images should not be evaluated with the same stringent requirements as those used for evaluating the ''best'' clinical images submitted for initial accreditation or reaccreditation.

As previously stated, FDA will require the accreditation body to evaluate the same attributes in the random clinical image review as are evaluated in the accreditation and reaccreditation clinical image review. As previously explained, the agency believes that accreditation bodies will have to adjust their scoring and pass-fail criteria to take into account that, due to the selection process, these examinations may not be representative of the best images a facility can produce. Such adjustments are appropriate and are permitted under the final regulations.

Section 900.4(f)(2)(iv) has been added to the regulations to clarify that the process for selection of images for random clinical image review may differ from the process for selection of images for accreditation and reaccreditation clinical image review.

(Comment 172). Two comments noted that different accreditation bodies already have instituted different selection criteria for their random clinical image review. One comment suggested that the review should be a combination of random (selected by the inspector) and nonrandom (selected by the facility) studies.

FDA recognizes that, under the interim regulations, each accreditation body has developed its own process for random clinical image review. Each is designed to best serve the needs of the accreditation body and its accredited facilities. The agency believes this

flexibility encourages efficient and effective review and has not changed the requirement. FDA believes that the selection of a combination of random and nonrandom studies would complicate the review process without a corresponding benefit. FDA is working with all of the accreditation bodies to further refine and improve their procedures and programs and will continue to do so. As noted previously, although each accreditation body can devise its own process for random clinical image review, that process must be reviewed and approved by FDA.

8. Consumer compliant mechanism (§ 900.4(g))

This paragraph describes the responsibilities of the accreditation bodies to ensure that serious consumer complaints are adequately addressed.

(Comment 173). The comments received were very similar to those received on § 900.12(h), which outlines the responsibilities of the facilities in this area. The comments on both of these paragraphs are discussed in section III.L.8 of this document in connection with § 900.12(h).

9. Reporting and recordkeeping (§ 900.4(h))

No comments were received on this paragraph, which describes the mechanisms by which the accreditation bodies provide information to FDA.

Consequently, this section was codified with only minor editorial changes.

10. Fees (§ 900.4(I))

This paragraph outlines the requirements that must be met by accreditation bodies to ensure that the accreditation fees are reasonable.

(Comment 174). Eight comments claimed that any fees are unreasonable, particularly for small practices, while another comment requested that multi-unit facilities be charged a higher fee.

The MQSA clearly intended that the accreditation process be supported through facility fees and that the agency be assigned the task of ensuring that such fees are reasonable (42 U.S.C. 263b(e)(1)(B)(iii)). FDA could not prohibit fees even if another source of funding were available. In response to the last comment, the agency notes that accreditation bodies can and do charge higher fees to multi-unit facilities.

*G. Evaluation (§ 900.5)*

This section states that FDA will evaluate the performance of each accreditation body annually, as required under the MQSA, and briefly outlines information that will be reviewed as part of the evaluation.

(Comment 175). One comment urged FDA to establish standard evaluation criteria and procedures to apply to the review of all accreditation bodies prior to establishing final regulations.

FDA agrees with this comment. Different accreditation bodies have different operational circumstances, e.g., geographic area and facilities served. Consequently, with FDA approval, they may have somewhat different programs. However, despite program differences, all accreditation bodies have to comply with the regulations governing accreditation body activities. Therefore, FDA has developed standard evaluation criteria that are being used to evaluate all accreditation bodies.

*H. Withdrawal of Approval (§ 900.6)*

This section outlines the enforcement actions available to FDA, including withdrawal of approval, if the agency determines that an approved accreditation body has not remained in substantial compliance with the requirements.

(Comment 176). One comment stated that ''major accreditation functions,'' upon which FDA could base a decision to withdraw an accreditation body approval, should be clearly identified. Another asked how FDA would verify that an accreditation body, whose approval had been withdrawn, had notified all of its facilities. Two other comments protested elimination of the mandatory schedule for accreditation bodies to submit corrective action plans for minor deficiencies.

Based upon its history of regulating accreditation body activities under the interim regulations, FDA believes that withdrawal of approval of an accreditation body would be rare and, in any case, would follow notice of problems and attempts to bring the body into full compliance. Should such a withdrawal occur, however, FDA would closely monitor the entire process of closing down the accreditation body operations, including the required notification of facilities.

FDA finds no basis for imposing mandatory schedules for correction of minor accreditation body deficiencies. Since approval of the first accreditation body in 1994, FDA has maintained a close working relationship with all the MQSA accreditation bodies. Accreditation body operational activities that might have been categorized as ''minor deficiencies'' have been resolved quickly and satisfactorily through direct communication with the accreditation bodies, rendering specific mandatory time limits for all such corrections unnecessary. The regulation continues to provide FDA with authority to specify a time period for any particular corrective action.

*I. Hearings (§ 900.7)*

This section describes the rights of accreditation bodies and facilities to hearings challenging adverse actions.

(Comment 177). Only one comment was received and it supported this section as written. Consequently, this section was codified with only minor editorial changes.

*J. Applicability (§ 900.10)*

This section of the proposal stated that the provisions of subpart B (which includes the facility quality standards) apply to all facilities under the jurisdiction of the United States that provide mammography services, except for those of the Department of Veterans Affairs (VA).

No comments were received directly on this section, although several comments on other sections questioned the exclusion of the facilities of VA. FDA notes that the wording of this section, including the exclusion, is based directly on the statute; the agency is unable to make any modifications (42 U.S.C. 263b(a)(3)(A)). However, VA is presently developing, under a separate legislative mandate, a program to ensure mammography quality equivalent to that required by the MQSA.

*K. Requirements for Certification (§ 900.11)*

This section establishes the requirement that mammography facilities must have an FDA certificate in order to operate lawfully and provides details on how to make application for a certificate and the time period during which the certificate may be effective. Only some of the provisions of this section drew comments. Discussion of these comments follows.

1. General (§ 900.11(a))

This paragraph requires mammography facilities to have certificates issued by FDA to operate lawfully. To obtain a certificate, facilities are required to meet the quality standards in § 900.12 and to be accredited by an approved accreditation body or other entity designated by FDA.

(Comment 178). One comment noted that FDA proposed to add that a facility may be accredited by an ''* * * other entity as designated by the FDA,'' that FDA claims to be concerned that at some time a facility may not have access to an accreditation body, and therefore an alternative accreditation body may be necessary for facilities to operate lawfully. The comment argued that there is no statutory basis for FDA to

appoint another entity and questioned under what circumstances a facility might not have access to an accreditation body. The comment closed by stating that, unless an urgent need for this provision can be clearly defined with limitations in its scope, it should be deleted from § 900.11 and elsewhere in the regulation.

The Secretary has discretion under the statute, both with respect to approving private nonprofit organizations and States as accreditation bodies and with respect to prescribing proof of accreditation. While the probability that facilities may not have access to an accreditation body is at present remote, there are neither guarantees nor requirements that any particular accreditation body will continue to serve in that capacity indefinitely. If one or more of the currently approved accreditation bodies were to become unable or unwilling to serve in that capacity, the agency wants provisions in place that will allow an alternative accreditation authority to be designated in order to ensure continuity and availability of quality mammography. Nothing in the statute precludes FDA from providing for this eventuality in its regulations or from designating other accreditation routes if that should ever become necessary to protect the public health.

(Comment 179). One comment stated that facility certification should allow interpreting physicians to work outside of the certified facility. The comment interpreted the proposal to treat an offsite reading room the same as an offsite mammography clinic and maintained that requiring the offsite reading room to be certified is burdensome and unnecessary.

FDA does not, at this time, intend to require separate certification of partial providers, such as an interpreting physician with an offsite reading room. The definition of a facility in § 900.2(q) includes partial providers, and FDA recognizes that there may be future advantages to separately certifying partial providers of mammography services. For example, it may be advantageous for a radiological practice with one or more interpreting physicians to be certified as a facility. By doing so, the practice's interpreting physicians could interpret mammograms from any other certified facility without those other facilities having to demonstrate the qualifications of the interpreting physician. At the present time, however, policies and procedures have not been established for accreditation and certification of partial providers. Consequently, as is the case under the interim regulations, an interpreting physician interpreting mammograms at a remote site will be included under the certificates of the mammography facility for which he or she interprets mammographic images. The physician will have to provide information to those facilities demonstrating that the requirements regarding his or her qualifications and any other applicable MQSA standards are met.

2. Applications (for Certificates and Provisional Certificates) (§ 900.11(b)(2))

FDA has amended the language in § 900.11(b)(1)(ii), (b)(2)(ii), and (b)(3)(iii) from ''will'' to ''may'' in order to parallel the statutory language that gives the agency discretion with respect to the issuance of certificates, provisional certificates, and extensions of provisional certificates to practice mammography. Although the agency has relied on accreditation body determinations in making decisions about whether to issue certificates, and intends to continue to do so, there may be situations in which FDA has additional information not available to the accreditation body or when the agency has reason to disagree with the accreditation body's evaluation of the facility as likely to perform quality mammography. In those circumstances, the agency retains discretion to deny a certificate even if the facility has become accredited. A new provision has been added at § 900.16 to implement the agency's statutory authority to deny certification to an accredited facility and to set forth the appeal procedures available to such facilities. In general, this paragraph requires that new facilities apply for accreditation through an approved accreditation body. Once a facility's application is accepted by the accreditation body, FDA may issue a provisional certificate that will allow the facility to perform mammography for not longer than 6 months in order to obtain the clinical images necessary for accreditation. A provisional certificate may not be renewed, but a facility may apply for a one time 90-day extension of the provisional certificate under certain circumstances.

(Comment 180). One comment suggested extending the 6-month provisional certification period for facilities that failed to be accredited, and a second comment stated that a facility should make substantial changes before being granted a second provisional certificate. A third comment recommended that FDA provide for renewal of provisional certificates at the discretion of FDA because some facilities may not complete accreditation, through no fault of their own, and may not qualify for a 90-day extension. A fourth comment recommended that provisional certification should be limited to one time only and described the 90-day extension as generous, allowing facilities a 9-month period in which to achieve full compliance.

In accordance with the MQSA, provisional certificates may only be extended for facilities that can demonstrate that access to mammography would be significantly reduced in the geographic area served by the facility, and only if the facility reports the steps that will be taken to qualify the facility for certification. In response to the first comment, therefore, FDA notes that there is no statutory provision for either an additional extension or the issuance of a second provisional certificate to the same facility.

The agency recognizes the dilemma noted in the comment concerning facilities that have been unable, perhaps for reasons beyond their control, to complete accreditation within the time period. The final regulations provide for reinstatement of certain facilities that failed accreditation or failed to complete the process during the first 6 months as new facilities. To qualify for reinstatement, the facility must submit and complete a corrective action plan developed to ensure correction of any deficiencies that led to failure. That corrective plan must be approved by the accreditation body and completed by the facility before the facility can be reinstated. On reinstatement, the facility is treated as a new facility, and issued a new provisional certificate that will allow it to produce mammograms for the clinical image review, which must be passed to obtain a 3-year accreditation and certification term.

FDA understands the concern of those comments that suggested facilities should not be given additional time or a second chance to establish that they are capable of doing quality work. The agency has had to weigh those concerns against competing concerns for access and the statutory emphasis on bringing facilities into compliance rather than putting them out of business. FDA believes that its reinstatement policy strikes the proper balance.

(Comment 181). Two comments agreed with § 900.11 as proposed. Another stated that a better definition is required to differentiate between those facilities that fail the second film review and are later reinstated, and those that fail and submit a new application under the pretense of being a new facility.

FDA and the accreditation bodies recognize the risk that might be created if a facility that failed accreditation is

issued a second provisional certificate under such pretense. FDA has instituted a variety of measures under the interim regulations to avoid such occurances, including close communication among accreditation bodies, between accreditation bodies and FDA, and a policy that each facility provide a history of previous accreditation activities with its application. The facility history requirement has been codified in the final regulation to require all applicant facilities to provide a complete history of prior accreditation activities, including a statement that all information and data submitted in the application is truthful and accurate, and that no material fact has been omitted. FDA expects to continue close communication among accreditation bodies and FDA to identify potential problems with this type of misrepresentation by facilities applying for accreditation.

(Comment 182). One comment recommended that § 900.11 be revised to include the MQSA provision that authorizes States to perform certification duties.

The MQSA does provide that States may serve as certifying bodies (42 U.S.C. 263b(q)). However, this subject is beyond the scope of these proposed regulations. Preparations are under way to draft regulations that will govern State agencies that wish to become certifying bodies, and the public will have an opportunity to comment on future proposals.

3. Provisional Certification Extensions (§ 900.11(b)(3)(i))

This paragraph describes the information a facility must submit to apply for a 90-day extension of its provisional certificate.

(Comment 183). One comment noted that the statute requires FDA to evaluate requests for 90-day extensions but that this provision stipulates that a facility shall submit its evidence in support of extensions to its accreditation body. The comment asked if it is FDA's intent to transfer this authority to the accreditation bodies. If it is not FDA's intent to transfer this authority to the accreditation bodies, the comment requested that, ''* * * its accreditation body * * *'' be changed to ''the FDA.''

The MQSA gives FDA the authority to evaluate and determine whether or not a facility qualifies for a 90-day extension of its provisional certificate, and FDA does not intend to transfer this authority to the accreditation bodies. However, the agency believes that it is in a better position to render valid decisions on requests for 90-day extensions if the accreditation body first reviews and makes a recommendation on the request in light of the accreditation body's detailed knowledge of the applicant and other facilities in the area. Therefore, the final regulation has been amended to clarify that the accreditation body will forward the facility's request for an extension, along with the accreditation body's recommendation. New § 900.11(b)(3)(ii) requires accreditation bodies to forward both requests and their recommendations to FDA within 2 business days of receipt of the request.

4. Reinstatement Policy (§ 900.11(c))

This paragraph contains the requirements and procedures for reinstatement of certification. Under this provision, FDA may permit a previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA, or that has had its certificate suspended or revoked by FDA, to apply to have the certificate reinstated.

(Comment 184). Four comments expressed concern that reopening a facility whose accreditation has lapsed may be difficult and that reinstatement is necessary so that such facilities may qualify as new facilities and thereby qualify for issuance of provisional certificates.

Reinstatement is the appropriate procedure for reopening a facility whose certification has lapsed. The MQSA only allows a provisional certificate to be issued to new facilities. As noted in section III.K.2 of this document, any facility that seeks reinstatement under this provision of the regulations will have to provide sufficient information to its accreditation body to establish that any problems in meeting the MQSA standards have been corrected, and that circumstances are such that the facility may qualify as a new facility for purposes of reinstatement. The decision about whether to apply for reinstatement is one that each facility must make based on its own circumstances. If the costs associated with such application are too high for any particular facility, it will forgo providing mammography services. On the other hand, if a facility has determined that it can improve its practice sufficiently to warrant reinstatement, or that it wished to resume a practice it voluntarily closed, reinstatement will permit such facilities to qualify for provisional certification as new facilities, and produce the clinical images that are necessary for 3-year accreditation and certification.

5. Justification for Reinstatement (§ 900.11(c)(1)(iii))

This paragraph requires a facility applying for reinstatement to justify its application.

(Comment 185). A comment asked how this would cover a facility that allowed its certificate to expire for reasons other than failure to comply or qualify.

FDA notes that a justification is required for all applications for reinstatement. A facility whose certificate has expired but that has had no deficiencies should submit a corrective action plan that explains the reasons for expiration and what it has done or will do to ensure that the facility meets the MQSA quality standards at the time of reinstatement.

6. Provisional Certificates to Reinstated Facilities (§ 900.11(c)(2) and (c)(3))

(Comment 186). Four comments raised concerns about the appropriateness of issuing provisional certificates to reinstated facilities, as the agency had proposed.

As a result of these comments, FDA has modified § 900.11(c) to read, ''Reinstatement policy. A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA, or that has had its certificate suspended or revoked by FDA, may apply to have the certificate reinstated so that the facility may be considered to be a new facility and thereby be eligible for a provisional certificate.'' This change is intended to make clear the need for a mechanism so that previously certified facilities that have instituted corrective actions or wish to resume services following voluntary cessation of mammography may be considered new facilities for purposes of issuing provision certificates as noted in section III.K.4 of this document. The agency has also changed the language of this provision from ''will'' to ''may'' in § 900.11(i)(2) to indicate that the agency retains discretion to accept facilities for reinstatement.

7. The 2-Year Waiting Period (§ 900.11(c)(4))

As proposed, this provision stated that if a facility's certificate is revoked, the facility may not be reinstated for 2 years if owned or operated by any person who owned or operated the facility at the time of revocation. Proposed § 900.11(c)(4) did not accurately reflect the MQSA requirement because it imposed the 2-year waiting period on facilities rather than on persons. The MQSA requires a 2-year waiting period before persons who own or operate a mammography facility at the time an act is committed that results in revocation of the facility's certificate may again own or operate a mammography facility (42 U.S.C. 263b(I)(3)).

Section 900.11(c)(4), therefore, has been changed to read, ''If a facility's certificate was revoked on the basis of an act described in 42 U.S.C. 263b(I)(1), no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility within 2 years of the date of revocation.''

(Comment 187). More than 40 comments expressed concern about how FDA would apply revocation and about the 2-year waiting period, which many comments suggested was excessive.

These and related comments to § 900.13 suggest an unwarranted expectation that suspension and revocation of certificates will be common practice in the event of noncompliance with the regulations. As noted above, the 2-year waiting period is mandated by the MQSA in the event of revocation of a certificate. That timeframe is not subject to modification by the agency. However, after more than 2 years of enforcement of the MQSA, FDA has not revoked any certificates and has only suspended the certificate of one operating facility. This should alleviate concerns that this enforcement action is one FDA is likely to use frequently or without cause.

The conditions under which FDA may suspend or revoke a certificate are set forth in § 900.14. In most cases, a suspension would precede a revocation action. As explained in the preamble to the proposed rule (61 FR 14878), suspension of a certificate generally would occur only when all other efforts to bring a facility into compliance with the regulations have failed or if continued operation of a facility would present a serious risk to human health. Suspension allows a facility to complete corrective action under accreditation body and FDA monitoring, and subsequently to be reinstated if those corrections are adequate. FDA generally intends to revoke certificates only when corrective and voluntary measures have failed and the agency has clear evidence that a facility cannot or will not practice quality mammography, or in the event the facility made false statements to FDA.

Unless other more serious events, as indicated above, necessitate otherwise, FDA will not revoke or suspend a certificate as a result of a finding that a facility is correcting, is willing to correct, or has corrected identified deficiencies. FDA's goal is to bring noncompliant facilities into compliance with the MQSA standards so that they can produce quality mammograms, rather than to close facilities. This goal reflects the intent of the drafters of the statute; the legislative history discussing the sanctions provisions, e.g., states that ''the first priority of the Secretary is to restore a mammography facility to compliance * * *'' S. Rept. 102–448, at 2 (1192).

(Comment 188). Ten additional comments stated that this section is frightening to many radiologists and asked who decides when voluntary action or lesser sanctions have proven ineffective, and if any third party reviews agency decisions. FDA will determine when voluntary or lesser sanctions have proven ineffective. The decision to suspend or revoke a certificate, however, is subject to challenge by the facility which is entitled to an informal hearing under 21 CFR part 16, and ultimately subject to judicial review.

*L. Quality Standards (§ 900.12)*

1. Personnel (§ 900.12(a))

This paragraph of the regulations establishes the training and experience requirements for physicians who interpret mammograms, radiologic technologists who perform mammography examinations, and medical physicists who have responsibility for periodically surveying the mammography equipment and overseeing the facility's equipment quality assurance program. The requirements include initial qualifications that must be met before an individual can begin independently providing mammography services to the facility and continuing qualifications that must be met on an ongoing basis. Facility recordkeeping requirements related to personnel are also discussed.

The final regulations generally retain the same requirements as were outlined in the proposal. In response to comments, however, the amount of training or experience needed to satisfy particular requirements has been adjusted in several places. The final regulations also establish a ''grand parenting'' provision for radiologic technologists.

a. *General comments on personnel section*

(Comment 189). General comments submitted by the public to FDA on § 900.12(a) offered contrasting views on the value of the personnel standards. One comment applauded the increased specificity of the proposal over the interim rules because the changes clarified what requirements the facility personnel had to meet. A second comment likewise noted that the requirements were ''well presented'' and clarified a number of issues. In contrast, a third comment stated that the more specific requirements made it harder for facilities to show that the requirements were met. A fourth comment found the requirements too prescriptive (but offered no suggestions on what could be deleted as unnecessary), but a fifth comment asked for even more specificity.

This variety of opinion illustrates the difficulty of striking the proper balance between making regulatory requirements specific enough so that it is clearly understood what is required yet general enough to allow for appropriate flexibility. FDA believes that the variety of comments indicates that significant changes to the general approach taken by the proposal are not warranted. However, the question of the proper balance between specificity and flexibility was reconsidered in response to comments on particular requirements.

(Comment 190). One general comment asked for clarification on who would be qualified to teach physicians, technologists, and physicists to use new technologies as they develop.

FDA believes that the new definition of qualified instructor (§ 900.2(oo)), discussed earlier, provides an adequate means for identifying qualified instructors. Under this definition, representatives of the manufacturers who develop new technology, along with the physicians, technologists, and physicists who worked with the technology while it was in the investigational stage, would generally be accepted as qualified to be the initial instructors in the use of the new technology. This approach is consistent with the general practice in the teaching of medicine.

(Comment 191). Several of the general comments on the personnel requirements were based on a misinterpretation of the proposed regulations or of the MQSA itself. Six identical comments argued for retaining the interim regulations, not because they opposed the proposed new requirements as such, but because they believed that the choice was between either the interim regulations or performance-based outcome measures, such as proficiency testing.

As explained previously, while comments were requested on the concept of performance-based outcome requirements, new performance-based requirements are not being proposed at this time.

(Comment 192). Another comment mistakenly believed the regulations made investigational use of MRI unlawful but, in fact, MRI procedures are not within the scope of the MQSA (42 U.S.C. 263b(a)(6)). Similarly, two general comments recommended removing of this section entirely,

reasoning that because FDA does not impose training or experience requirements on users of other medical devices, there was ''no possible justification'' for mammography being treated differently.

In fact, however, Congress has directed that mammography be treated differently and required the government to establish personnel standards (42 U.S.C. 263b(f)(1)(C), (D), and (E)). The MQSA embodies Congress's determination that such standards would help ensure that mammography services are provided only by those qualified to do so.

b. *Comments on interpreting physicians (§ 900.12(a)(1))*

The final regulations for interpreting physicians establish initial professional, educational, and training qualifications, as well as requirements for continuing experience and education. Although neither a national standard nor a continuing performance competency test for mammography interpretation currently exists, the requirements of § 900.12(a)(1) for interpreting physicians will provide baseline standards to help ensure the reliability and accuracy of interpretation of mammograms for women throughout the country.

The final regulations are generally the same as those proposed. In response to comments, however, some new provisions have been added and several others were revised as follows: (1) Sixty rather than 40 hours of documented medical education in mammography must be Category I; (2) a new section was added to clarify the use of CME obtained by teaching medical education courses; (3) the mechanism to document continuing experience and education requirements has been revised to reduce the administrative burden on facilities; (4) additional pathways for physicians who need to reestablish their qualifications have been added; and (5) the initial qualifications have also been modified to clarify the conditions for ''grand parenting'' of interpreting physicians and the initial experience requirement for some residents. These changes from the proposal will be discussed below in connection with the appropriate provisions.

(Comment 193). Over 100 comments stated that only radiologists should be permitted to work as interpreting physicians.

After considering these comments, FDA continues to believe that this additional limit would not be in the interest of public health. Currently, there are some physicians, not formally trained as radiologists, who have met the requirements of the interim regulations and are competently interpreting mammograms. Therefore, FDA believes that it would be unnecessarily restrictive to limit interpreting physicians to radiologists. By requiring all physicians wishing to interpret mammograms to meet the same baseline quality standards of training, experience, and continuing education, the goal of ensuring quality mammography can be achieved without arbitrary restrictions relating to the specialty of the particular physician.

(Comment 194). One comment suggested that interpreting physicians who practice at more than one facility should be required to provide proof of credentials and qualifications only one time, rather than providing this material for each facility with which the physician is affiliated.

FDA disagrees for a number of reasons. First, the MQSA requires mammography facilities to meet certain requirements, including establishing that its personnel are qualified under the statute. Because it is the facility that is responsible and will be inspected, it is necessary for that facility to have documentation for all the interpreting physicians who work there. In addition, while several of the initial personnel requirements do not change over time, some, such as medical licenses, are time limited and need to be updated. Similarly, if the continuing experience and education requirements are not updated by the personnel, the facility can be cited for violations of the MQSA.

(Comment 195). One comment stated that interpreting physicians should be required to pass an annual, documented visual acuity test. In response to this suggestion, FDA notes that while visual acuity is important, there are no standards as to what would constitute acceptable visual acuity. The agency does not believe it is necessary to become involved in those details of physician fitness that are better handled by licensing authorities.

(Comment 196). Two comments stated that training in ultrasound should be required for interpreting physicians as part of the accreditation program.

Under the MQSA, FDA's authority to regulate mammography is limited to radiography of the breast. Therefore, requirements related to ultrasound have not been included in personnel or other facility standards.

(Comment 197). Two comments supported FDA's position that all physicians reading mammograms should be required to meet the same training standards. The comments stated that this is particularly important with regard to locum tenens and that facilities may need to be reminded that their locum tenens should provide all appropriate documentation prior to beginning independent interpretation.

FDA agrees that all personnel are required to meet the same standards regardless of whether they work full or part-time and facilities must make sure that all the personnel at their facility meet the necessary requirements.

The quality standards for interpreting physicians are divided into four sections: Initial qualifications; continuing experience and education; exemptions; and reestablishing qualifications.

Under § 900.12(a)(1)(i), the first qualification for an interpreting physician is a State license to practice medicine.

(Comment 198). Over 50 comments recommended that the proposal be changed to state that all interpreting physicians should be licensed in ''the'' State in which they practice.

FDA does not believe the proposed regulation should be amended. Although § 900.12(a)(1)(I)(A) requires the interpreting physician to have ''a'' State license to practice medicine, in the vast majority of cases, State laws require a physician to be licensed in ''the'' State in which he or she is practicing. If the State in which the mammography facility is located is different from the State that issued the license, a physician may have to meet additional State requirements in order to practice medicine lawfully at that facility. With respect to physicians practicing in Federal facilities, a valid State license from any State is sufficient. However, the Federal employee would be unable to practice outside the Federal facility unless the physician also fulfilled the requirements of that State for the practice of medicine.

Under § 900.12(a)(1)(I)(B), the second initial qualification for interpreting physicians is board certification or 3 months of documented formal training in interpreting mammograms. The training is to include radiation physics (including radiation physics specific to mammography), radiation effects, and radiation protection.

(Comment 199). Over 80 comments stated that all interpreting physicians should be board certified radiologists. The comments stated that being board certified establishes that the person reading the mammogram understands all the basic principles of physics and breast anatomy and that this would ensure the most accurate readings. In contrast, four comments disagreed with the use of specialty board certification as a measure of qualification. These comments generally argued that requiring specialty board certification will adversely affect patient access to

medical services. These comments also stated that many individuals certified by the ABR did not receive formal training in current mammography techniques because their training predated the development of modern mammography standards. One comment stated that individuals certified by ABR before 1989 were not examined in mammography techniques as part of their board certification process and that the oral examination process of ABR certification is highly subjective and influenced by personality and demeanor. The comment also claimed that ABR has awarded board certification through the ''Class A'' rule, in which favorite candidates were certified without any examination process, and that ABR does not adhere to ''due process'' by using subjective oral examinations to certify candidates.

In response to criticism of board certification as fulfillment of an initial quality standard, FDA notes that the statute specifically recognizes board certification as one of the mechanisms for meeting a portion of the interpreting physician requirements (42 U.S.C. 263b(f)(1)(D)(I)(I)). In addition, the agency continues to believe that board certification is a valid indication of overall competency. FDA recognizes that some earlier board examinations may not have included testing in mammography. FDA also recognizes that board certification that includes mammography testing cannot ensure the accuracy of outcomes in clinical mammography practices; no training or certification program can guarantee proficiency in all cases. However, board certification is evidence that the physician is knowledgeable in the basics of diagnostic radiology and can serve as a foundation for the additional requirements specific to mammography that interpreting physicians must meet under FDA's regulations. The ''Class A'' rule referenced in the comments was used in the mid 1930's during the startup phase of the ABR in order to certify those outstanding physicians who were experienced in the field of radiology. This rule has not been used in over 50 years and, since 1940, all candidates have had to take examinations. FDA does not believe that the ''Class A'' rule has a significant bearing on the radiologists practicing today. While FDA does agree that there is some subjectivity in all tests, the agency is satisfied that the accepted boards represent a valid means of determining general competency. FDA disagrees with the assertion that the boards do not adhere to due process. Formal appeals processes are available to those candidates who wish to dispute a board decision. For all these reasons, FDA believes that board certification must remain an acceptable way to meet a portion of the initial qualifications for mammography personnel.

In response to comments that questioned the validity of permitting physicians who are not board certified to practice mammography, FDA notes that Congress directed FDA to establish an alternative pathway to board certification (42 U.S.C. 263b(f)(1)(D)(I)(II)). FDA believes that the 3 months of documented formal training will ensure that all physicians interpreting mammograms have received an adequate amount of instruction.

(Comment 200). Several comments, including a consensus of NMQAAC, stated that the 3-month training alternative was appropriate, but that the topics, number of hours for each topic, and the qualifications for those teaching these topics should be specified. NMQAAC and others believed that this training should be limited to that obtained in a radiology residency program. Some, including members of NMQAAC, said that the physics training should only be obtained from a medical physicist. One comment suggested that FDA require a minimum of 200 hours of physics training.

After considering all the comments, FDA has concluded that specifying the precise number of hours spent on each topic would be too prescriptive and would curtail the ability of training programs to individualize their curricula. FDA also believes that restricting training to radiology residency programs or, in the case of physics, to training by a medical physicist, would limit adequate training opportunities. FDA's experience under the interim regulations has led the agency to conclude that adequate training opportunities are also available to physicians who are not involved in radiology residency programs.

(Comment 201). Several comments stated that FDA should notify the certifying boards, residency programs, facilities, and personnel of the new requirements so that sufficient training and proper documentation are given to all physicians. One comment suggested phasing in the 3-month training requirement to allow program directors the time needed to adjust their curricula. One comment stated that physicians should be made aware that it is their responsibility to keep track of training and continuing education.

FDA agrees with the general points being made by these comments. The agency has and continues to provide the appropriate boards, programs, facilities, and personnel with the information they need to meet and document the requirements of the MQSA. Programs should have an adequate amount of time to adapt to the new requirements, which will not go into effect until 18 months after publication of this rule.

(Comment 202). Several comments suggested that 2 months of documented formal training in the interpretation of mammography, the current requirement under the interim regulations, is more than sufficient and that the increase to 3 months was excessive. One comment proposed that the 3 months be reduced to 2 months for those who have been reading mammograms consistently for 5 years or more. Another comment suggested that individuals who have qualified under the interim regulations should not be required to reapply or provide further documentation beyond that which was previously submitted to FDA.

FDA has received advice from NMQAAC, AHCPR, and others that 2 months of training for new physicians is insufficient to cover all the required topics. AHCPR has advocated 4 months of training. FDA believes that the increase from 2 to 3 months is appropriate and can be instituted by residency and other training programs without undue burden. As explained below, interpreting physicians who began independent interpretation under the interim regulations are considered to have met the initial qualifications under the final regulations. There will be no need for them to reapply or supply additional documentation to FDA. Also, because the 3-month requirement applies only to new interpreting physicians, anyone with the suggested 5 years of consistent experience should have qualified previously under the interim regulations.

(Comment 203). One comment stated that any physician who is not a radiologist should be required to demonstrate competency in mammography through an examination, in addition to the training requirements.

FDA declines to accept this suggestion. The agency has concluded, as discussed earlier, that adequate training programs can ensure that an interpreting physician has skills to practice mammography, regardless of his or her initial specialty. In addition, FDA agrees with the many public comments the agency received concerning the difficulties associated with physician competency testing as a qualifying method. At the present time, a suitable test to judge the competency of interpreting physicians does not exist. This may become an option in the

future, but until it does, training requirements appear to offer the most satisfactory method of establishing quality standards.

(Comment 204). One comment recommended that all interpreting physicians be urged to meet exactly the same criteria without regard to board status. The comment suggested that the original alternative pathway established by the interim regulations, 2 months of documented training in interpreting mammograms, 40 hours of CME in mammography, and 15 hours of Category I CME per 3-year period, should be required for all interpreting physicians, even those who are board certified.

In response to this comment, FDA notes that the MQSA establishes an alternative rather than a cumulative requirement in this matter. While FDA always encourages individuals to strive for excellence by exceeding the requirements, either of the two pathways (board certification or 3 months training) will be sufficient training to meet this portion of the initial requirement. All interpreting physicians, including those who are board certified, are required to comply with the initial and CME requirements. This has been true under the interim regulations and will continue to apply under the final regulations.

The third initial requirement for interpreting physicians, § 900.12(a)(1)(i)(C), is 60 hours of documented medical education in mammography, including instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and QC. Unlike the proposed rule, the final regulation requires that all 60 of these credits be Category I CME. At least 15 of these 60 Category I CME hours must have been acquired within the 3 years immediately prior to qualifying as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category I CME and will be accepted if documented in writing by an appropriate representative of the training institution. The specific mammographic modality training requirement that was included in the proposed rule (61 FR 14907) has been deleted from this part of the final regulations because it is duplicated in § 900.12(a)(ii)(C).

(Comment 205). Several comments agreed with § 900.12(a)(1)(I)(C) as originally proposed, while others, including NMQAAC, maintained that all 60 hours of credit should be Category I in order to provide consistency in the quality of the training. Several comments recommended that the number of hours spent in each subject be specified. Many comments said that the 40 hours already required by the interim regulations are sufficient and that raising the number to 60 would have a negative impact on cost and the availability of mammography services. Several stated that Category II credit is just as educational as Category I and should be allowed. One comment questioned the value of CME requirements generally, stating that most of what is said at conferences and courses is repetitive.

FDA disagrees with the comment questioning the usefulness of CME. The agency believes that 60 hours of training is in keeping with current trends in training and the emergence of new technologies. Because this expanded requirement will apply only to new interpreting physicians and time spent in residency specifically devoted to mammography will be accepted toward meeting this requirement, FDA does not believe that the number of hours required will have a negative impact on availability of services. FDA has been persuaded by the comments and its experience under the interim regulations that all 60 hours should be Category I. Category I CME credits are generally those that offer more formal training and provide a solid basis for the ongoing maintenance and growth of the interpretive skills of the physician. While Category II hours may be useful, the variability of such education and the difficulty in documenting such training convinced FDA to strengthen the requirement by making all 60 hours Category I. FDA has not specified the number of hours required to be spent in each subject because the agency believes that this would be too restrictive and would limit the ability of physicians and programs to individualize training.

(Comment 206). Three comments recommended that FDA clarify that the persons providing this training be in active practice and individually fulfill these qualifications.

FDA disagrees with these comments. It is not necessary for all of the persons providing the training to meet the qualifications of interpreting physicians. For example, those teaching basic breast anatomy, pathology, or physiology do not have to be interpreting physicians to provide expert instruction in those subjects.

(Comment 207). One comment asserted that 40 or 60 hours of training does not qualify someone to read a mammogram.

In response to this comment and others that questioned the clinical value of any particular requirement, FDA agrees that 60 hours of training alone does not qualify a physician to read a mammogram. However, this is only one of a series of requirements; the combination of requirements relating to training, experience, and continuing education is intended to provide assurance that those interpreting mammograms meet baseline quality standards.

The final initial qualification relates to experience reading mammograms. Section 900.12(a)(1)(I)(D) requires the qualifying physician to interpret or multi-read at least 240 mammographic examinations within the 6 months immediately prior to the date that the physician qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician. The intent of this requirement is to demonstrate recent supervised experience before the physician begins to interpret mammograms independently. Although the language has been clarified, this requirement is essentially unchanged from the proposal.

(Comment 208). Several comments misinterpreted the proposed requirement to mean that interpreting physicians would have to interpret 240 studies under direct supervision any time he or she changed facilities.

That interpretation is incorrect. This is an initial requirement for the individual prior to beginning practice as a new interpreting physician and is independent of the number of facilities at which the physician works.

(Comment 209). Two comments suggested that the requirement to interpret 240 mammograms under direct supervision should be revised to be 240 within the last 2 years of training prior to qualification as an interpreting physician. The comments stated that the requirement of 240 mammograms in the last 6 months of training is virtually impossible for any residency program with more than 6 residents in any postgraduate year.

FDA agrees. Both the proposal and the final rule include a provision that allows residents to meet this requirement in the last 2 years of their radiology residency programs if they become appropriately board certified at the ''first allowable time.'' See discussion of § 900.12(a)(1)(iii)(B) that follows.

(Comment 210). One comment asked for clarification concerning the 240 mammograms that a physician must interpret for initial training. The comment wanted to know if two

readings of a mammogram can be counted as two interpretations.

Multi-reading, as defined in § 900.2(ff), allows two or more physicians to read the same mammogram and each may count it as one interpretation. However, one physician may not read the same mammogram twice and count it as two separate interpretations.

(Comment 211). Several comments stated that physicians should be given a document stating the number of mammograms read after completing residency training. This would assist the facility in making sure physician requirements are met.

FDA agrees that this is a good idea and has and will continue to inform residency programs of the benefits of such a policy. However, FDA does not regulate residency programs and cannot require that such programs provide this documentation.

(Comment 212). Several comments recommended that the supervised interpretation required for initial qualification be performed under someone qualified to teach interpretation. NMQAAC recommended that this training be obtained in a radiology residency program.

While the majority of interpreting physicians will receive this training in their residency program, FDA believes that restricting such training to only those in radiology residency programs would unnecessarily limit the availability of adequate training opportunities. As previously discussed, FDA's experience under the interim regulations has led the agency to conclude that adequate training opportunities exist outside of radiology residency programs.

Section 900.12(a)(1)(ii)(A) is the first of the requirements established to ensure that interpreting physicians, who have met initial requirements, maintain their qualifications as they practice mammography. Under this requirement, in order to continue to qualify under the MQSA rules, interpreting physicians are required to have interpreted or multi-read at least 960 mammographic studies in the previous 24 months. Although the wording has changed somewhat from the interim and the proposed final rules, there has not been a substantial change in this requirement. The proposal has been amended so that a total of 960 examinations have to be interpreted in the previous 24 months instead of the previous formulation of an average of 40 examinations per month over 24 months. This requirement continues to provide flexibility to physicians who find they need or want to interrupt their practice for periods of time for personal or professional reasons (e.g., maternity, illness, sabbaticals). The wording has also been revised to clarify that the 24 months can be measured in any of the following ways: From the date of the annual inspection of the facility at which the interpreting physician works; from the last day of the calendar quarter immediately preceding the annual inspection date; or from any date in between the two. These options will ease the paperwork burden on the facility and allow the facility to gather and monitor this information in a more efficient manner. For example, rather than tabulate daily or monthly totals, the facility may wish to tabulate this data only at the end of the quarter prior to the next expected annual inspection. FDA strongly recommends that facilities use the same tabulation method and the same option for determining the 24-month period for all of their personnel for simplicity and to help achieve consistency within the facility. However, this is not required.

(Comment 213). Ten comments stated that diagnostic radiology graduates who pursue a fellowship in a field other than mammography face a difficult situation and will unnecessarily burden supervising physicians when they resume mammographic interpretation at the end of these fellowships. The comments stated that interpreting physicians who meet the requirements for 2 months training during residency and pass the certifying board exams have been adequately educated, and their interpretations do not need to be supervised when they resume reading mammograms.

FDA disagrees and has received advice from many groups, including NMQAAC, that continuing experience is a necessary requirement to help ensure the accuracy of mammographic interpretation. FDA believes that it is in the best interest of the patient for physicians who have not interpreted the required number of studies in the previous 24 months to be supervised prior to independent interpretation. This requirement applies equally to radiology fellows who have been outside the practice of mammography as well as to interpreting physicians who stop practicing for a significant period of time.

(Comment 214). FDA received 17 comments addressing the issue of interpreting an average of 40 mammographic examinations per month. Of these, 7 agreed with the proposal or recommended a higher number of examinations, while 10 asserted that the requirement was unnecessary, or that the number was too high and would adversely effect low volume or rural facilities.

FDA believes that all women, including those in rural areas, are entitled to the same quality of care. The agency cannot support lower standards for particular facilities. The agency also believes that it will not be difficult for most physicians to meet this continuing qualification, even for those in rural areas. The agency also wants to clarify that this is a physician requirement, not a facility requirement. Interpreting physicians who provide services to low volume facilities can interpret films at more than one facility to attain the required number of examinations. Multi-reading of images previously interpreted by another physician is also accepted as a way of meeting this requirement. However, the physician may not count interpretation of the same mammogram more than once. Currently, under the interim regulations, multi-reading is being used successfully by some interpreting physicians to meet this requirement. For all of these reasons, the agency believes this requirement will not cause a mammography access problem.

FDA recognizes that numbers alone cannot guarantee competency, but believes that the experience a radiologist accumulates through interpreting a certain minimum number of studies is a necessary aspect of the qualification process. In § 900.12(f), FDA has issued requirements for the establishment and implementation of a medical outcomes audit for individual physicians. When used properly, this type of monitoring can further improve the reliability, clarity, and accuracy of interpretation of mammograms.

(Comment 215). One comment stated that FDA should not set a maximum number of films that can be read by an interpreting physician.

FDA agrees. There is nothing in the MQSA or the regulations that establishes such a limit.

Section 900.12(a)(1)(ii)(B) requires interpreting physicians to further maintain their skills by teaching or completing at least 15 Category I CME credits in mammography in the previous 36 months. This training must include at least six Category I continuing education credits in each mammographic modality used by the physician. As with the continuing experience requirement, FDA has modified the language of the proposal to allow facilities greater flexibility and efficiency in tabulating this data for interpreting physicians working at the facility.

(Comment 216). Seventeen comments raised questions about CME in

technologies that do not fall within the scope of the MQSA, such as ultrasound or MRI. These comments asked whether 6 hours of CME in each of these breast imaging applications is required and, if not, can such continuing education in these technologies nevertheless be used to satisfy the CME requirements. Two comments suggested further clarification of what activities are acceptable as CME.

Because these technologies are outside the scope of the MQSA, there is no requirement for a physician to have continuing education in them in order to qualify under the MQSA. CME in such technologies may, however, be applied to fulfill a portion of the continuing education requirement if that continuing education is likely to aid the physician in the understanding of mammographic breast cancer detection. CME in ultrasound and MRI of the breast would fall into this category and could be used to fulfill a portion of the continuing education requirement.

(Comment 217). Several comments supported the requirement for interpreting physicians to obtain at least 15 Category I CME every 3 years. Others asserted that there was no clear basis for the requirement. One comment stated that the interim rule requirements regarding completion of CME are unnecessarily bureaucratic because one's knowledge does not suddenly expire with an arbitrary deadline. Two comments maintained that the cost and number of man-hours required by these regulations is a serious burden, particularly considering that there is no scientific evidence that these efforts will result in improved medical care. Another comment indicated that training in each mammographic modality is already part of training programs and, for the vast majority of individuals, training is unnecessary because they have been providing services in these modalities for many years. This comment and others asserted that requirements for additional documentation of continuing education is unnecessarily burdensome for physicians who can demonstrate that they have completed an accredited program and have appropriate certification.

FDA has been advised by NMQAAC and professional organizations, such as ACR, that continuing education is necessary in order to maintain skills in an ever changing field of medicine. The agency agrees and notes that the statute, 42 U.S.C. 263b(f)(1)(D)(ii), establishes a general requirement for continuing education. FDA has required that the credits be Category I CME in order to ensure that continuing education is more formal, can be documented, and contributes to the development of the professional skills of the physician. FDA believes that there are many avenues for obtaining this education and that the cost and man-hours required will not be overly burdensome on physicians. This requirement, as it relates to timeframes for monitoring compliance, has been modified from the proposal in a manner similar to that for continuing experience. This change will clarify that facilities need not update CME for physicians on a daily or monthly basis. FDA has evaluated many different scenarios for use as averaging periods and reviewed this particular issue with NMQAAC.

(Comment 218). Several comments recommended that CME be averaged over a fixed 3-year period rather than on any given day. FDA notes that under a fixed 3-year period, physicians could acquire CME credits at the beginning of one period and at the end of the next, resulting in a span of almost 6 years in which the physician had not received any CME.

FDA has concluded that the present floating 36-month period is more likely to contribute to quality mammography. A floating 36-month period eliminates the possibility that physicians will go for extended periods of time without continuing education. At the same time, it still permits physicians to devote their time to longer courses, when they are available, and to update their CME when the best opportunities for training arise, regardless of when that offering is made within the 36-month period.

(Comment 219). One comment recommended that interpreting physicians be tested every 2 years to keep up to date with all changes in the discipline.

FDA believes that, at the present time, there is no adequate proficiency test to judge the continuing competency of interpreting physicians. For the foreseeable future, continuing experience and education requirements appear to offer the most satisfactory method for establishing compliance with these personnel standards.

(Comment 220). One comment requested stricter control over acceptable ways for an interpreting physician to obtain continuing education units in mammography. The comment claimed that interpreting physicians who do not attend actual view box classes, but get their CME from a syllabus, have higher call back rates on films that they interpret. The comment recommended that all interpreting physicians be required to attend actual hands-on training seminars.

FDA disagrees with this comment. After discussion with NMQAAC, the agency believes that limiting continuing education to hands-on training would greatly restrict the ability of many interpreting physicians to obtain such training, without providing a documented corresponding benefit. FDA believes that syllabi and other types of training can be as beneficial as hands-on training.

(Comment 221). Several comments, including some from NMQAAC, indicated that a better definition of modality was needed. In order to reduce any confusion, the term ''modality'' has been changed to ''mammographic modality'' to emphasize that the term does not refer to nonmammographic techniques, such as ultrasound or MRI, that may be used to examine the breast.

Several comments stated that the requirement for six Category I CME credits in each mammographic modality is impractical and recommended that the continuing education qualification be left at 15 Category I credits in breast imaging, as required under the interim regulations. The comments went on to say that radiologists do more than just breast imaging and that, in any case, breast imaging courses do not list their credits by mammographic modality.

FDA believes that the requirement for six Category I CME credits in each mammographic modality used by the interpreting physician is consistent with the goal of maintaining expertise. At the present time, there are only two mammographic modalities available, film screen and xeromammography. More than 99.5 percent of facilities are using only one mammographic modality, namely film screen. Currently, because there is only one mammographic modality generally used, this requirement would not create an additional burden for the vast majority of physicians. When digital mammography becomes available, those physicians using both film screen and digital modalities would have to acquire at least six category I CME credits in each of these mammographic modalities over a 3-year period. If three different mammographic modalities become available and all three were used by an interpreting physician, that physician would have to accumulate at least 18 Category I credits in the previous 36-month period, 6 in each mammographic modality. It is true that designation of CME credits in mammographic modalities other than film screen is not commonplace at the present time. However, as courses become available in digital mammography, the number of

hours devoted to the new mammographic modality can be documented by the course sponsors. In the meantime, keeping a copy of the program outline listing the lecture titles will serve as adequate documentation for the MQSA inspectors.

Section 900.12(a)(1)(ii)(C) requires that, before using a new mammographic modality in his or her practice, the interpreting physician must have at least 8 hours of training with that mammographic modality.

(Comment 222). Several comments, including those from NMQAAC, supported this requirement, while many others wanted additional clarification or stated that 8 hours was excessive because similar skills are used in all mammographic modalities. Several comments asked how this training could be obtained and documented in light of the fact that CME courses do not presently provide such training or give certificates in such detail.

FDA believes that 8 hours of training in a new mammographic modality is an appropriate baseline. FDA agrees that there is overlap in the skills necessary to interpret studies done by different mammographic modalities. However, there are enough differences to justify this additional education. Before a physician begins to interpret images produced by a particular mammographic modality, the agency believes that the physician should have specific training in the interpretation of such images. Until new mammographic modalities become widely available, there may be a paucity of formal CME courses giving such instruction. FDA recognizes this and, therefore, has not required that this be Category I CME. This will allow other entities, such as equipment manufacturers, to supply the initial training. In this way, physicians and other personnel will be able to obtain the required 8 hours of training from sources intimately associated with the new equipment they will be using. Formal category I CME courses will also be accepted. As mentioned previously, for those courses that do not list the CME by mammographic modality, the program outline can serve as documentation of how much time was spent in the new mammographic modality.

(Comment 223). Many comments interpreted this requirement to mean that physicians must receive 8 hours of CME credit in xeromammography, which is now used very infrequently. These comments misinterpreted this requirement, which applies only when a physician begins using a mammographic modality in which he or she has not been previously trained.

Because xeromammography is seldom used today, it would be extremely unlikely for an interpreting physician to begin using this mammographic modality for the first time. It would only be in this unlikely circumstance that the interpreting physician would have to obtain 8 hours of xeromammographic training.

(Comment 224). One comment suggested that, in addition to this requirement, the physician should also be required to interpret a specified number of mammograms from the new modality under the supervision of a qualified interpreting physician before independent interpretation.

FDA does not support this additional requirement. While supervised interpretation might benefit interpreting physicians who begin using a new modality, the agency does not believe this qualification needs to be mandated for physicians who are already experienced in interpreting mammograms through another mammographic modality. Such a requirement could hinder the introduction of new mammographic modalities by raising the cost of initial training and significantly reducing access.

With the concurrence of NMQAAC, § 900.12(a)(1)(ii)(D) was added to the final regulations to clarify that CME earned by teaching a particular course could be counted only once towards the 15 credits for an interpreting physician under § 900.12(a)(1)(ii)(B).

Section 900.12(a)(1)(iii) establishes exemptions from certain personnel requirements for interpreting physicians in specific cases. Section 900.12(a)(1)(iii)(A) exempts physicians who qualified under the interim regulations from the new and additional initial requirements in § 900.12(a)(1)(i): The additional month of training for physicians using the alternative pathway; the additional 20 hours of CME; and the requirement that 15 Category I CME credits must have been acquired in the 3 years immediately before qualifying as an interpreting physician.gi11(Comment 225). One comment opposed ''grand parenting'' of interpreting physicians who qualified under the interim regulations because of the ''minimal standards'' required under the interim regulations. Another comment agreed with the regulation as written.

In order to ensure continuing and uninterrupted availability of mammographic services and because FDA's inspections over the past 2 years do not demonstrate problems with these physicians, FDA is permitting those interpreting physicians who qualified under the interim regulations to continue to interpret mammograms, provided that they maintain the continuing experience and education requirements in § 900.12(a)(1)(ii). As discussed in connection with other personnel requirements, the agency has determined that qualifying standards should be raised as new personnel qualify in the future because of increasingly complex and changing technologies. The agency has also concluded that the need for continued availability of services, fairness to practicing personnel, and the compliance record of facilities with the MQSA over the past years justify permitting personnel who qualified under the interim regulations to continue to practice. FDA believes the final rule strikes the proper balance among these considerations and is in the best interest of the public health.

Section 900.12(a)(1)(iii)(B) establishes another exemption in response to concerns raised by members of NMQAAC and others that the initial experience requirement in § 900.12(a)(1)(i)(D) may pose a problem for residency programs that schedule mammography rotations earlier than the final 6 months in the residency program. Instead of requiring the initial reading experience to be completed in the last 6 months prior to initial qualification, this provision has been amended to permit some residents to satisfy the requirement by having interpreted at least 240 mammographic examinations under the direct supervision of an interpreting physician in any 6-month period during the last 2 years of the residency. This exemption is available only to those residents who successfully become board certified at the ''first allowable time,'' which means the earliest opportunity provided by an eligible certifying board. The physician who qualifies for this exemption would become responsible for fulfilling the continuing education and experience requirements of § 900.12(a)(1)(ii) beginning on the date of that physician's board certification in diagnostic radiology, provided the other initial requirements are satisfied. If the physician does not become board certified at the first allowable time by the certifying board, the exemption does not apply and the physician must interpret 240 mammographic examinations under the direct supervision of an interpreting physician within a period of 6 months immediately prior to initial qualification as an interpreting physician.

(Comment 226). Several comments said that this exemption was still too restrictive and recommended that the

requirement be expanded to allow reading at any time during the residency, rather than within the final 2 years. Some believed the requirement was too stringent because the exemption was available only to those residents who became board certified at the ''first allowable time.'' One comment asserted that residents who did not pass the boards at the first allowable time were no less qualified to perform mammography than the resident who successfully completed the boards, unless the physician failed the mammography section.

After considering these comments, FDA has concluded that the final regulations provide sufficient flexibility. The exemption permits residents to interpret the required number of mammograms in any 6-month period during the last 2 years of their residency program, as long as they become board certified the first time they are eligible. This allows residency programs flexibility in scheduling their residents and prevents the scenario of having all senior residents doing their mammography rotation during the same 6-month period. FDA believes that mammography interpretations performed more than 2 years before completion of a residency program are not recent enough to qualify as initial experience, even in the situation where residents become board certified at the first allowable time. FDA expects that the 2-year time period will allow participants in virtually all residency programs to comply with the regulation. A baseline standard in general radiology would be ensured by the fact that residents qualifying for this exemption would have passed their certification boards, including the mammography section. Those residents not successfully completing their board certification at the first allowable time would not be eligible for this exemption.

(Comment 227). Several comments stated that this exemption should be revised to allow an individual completing a radiology residency program and progressing on to a 1-year fellowship to qualify under § 900.12(a)(1)(iii)(B).

FDA disagrees and believes that meeting the initial requirements and qualifying for this exemption is independent of any additional training the individual may obtain. As discussed previously in connection with continuing experience requirements, FDA believes it is in the best interest of public health that interpreting physicians, including radiology fellows who have been outside the field of mammography, have relatively recent experience before beginning or resuming independent interpretation.

Section 900.12(a)(1)(iv) provides a method for physicians to reestablish their qualifications as interpreting physicians in the event they do not maintain the continuing experience or education requirements. Section 900.12(a)(1)(iv)(A) requires the physician who has failed to meet the continuing experience requirement to interpret or multi-read either 240 mammographic examinations or enough mammographic examinations to bring the physician's total up to 960 for the prior 24 months, whichever is less. These interpretations shall be under the direct supervision of an interpreting physician and occur within the 6 months immediately prior to resuming independent interpretation. This section was modified from the original proposal to be consistent with policies that have been successfully implemented under the interim regulations to deal with physicians who need to reestablish their qualifications.

Section 900.12(a)(1)(iv)(B) requires physicians who have not maintained the continuing education requirement to obtain a sufficient number of Category I CME credits in mammography to bring their total up to the required 15 credits in the previous 36 months. A physician who fails to maintain continuing experience or education requirements may not serve as an interpreting physician until he or she reestablishes those qualifications.

(Comment 228). Two comments stated that there should be a penalty for physicians who do not meet the requirements in the appropriate timeframe.

FDA believes that temporary disqualification from independent interpretation is the most effective and appropriate penalty in these situations. The purpose of the regulations is to ensure that personnel meet baseline standards. Under the final regulations, physicians who do not maintain the required number of interpretations or earn the necessary CME credits must cease independent interpretation of mammograms until such time as they complete a sufficient number of supervised interpretations or CME to meet the requirements. This is the best way to protect the public health. FDA disagrees with the comment that the physician should be penalized in some additional manner for not having maintained the continuing requirements.

c. *Radiologic technologists § 900.12(a)(2)*

FDA's interim and final regulations for radiologic technologists performing mammography both seek to ensure that technologists: (1) Possess adequate general qualifications for performing radiologic examinations; (2) possess adequate specific qualifications for performing mammography examinations; and (3) maintain these qualifications over time. The changes from the interim regulations to the final regulations were primarily clarifications with some additional requirements to address concerns that became apparent as the interim regulations were implemented. In response to comments on the proposed rule, a number of changes have been made. A ''grand parenting'' provision has been added to qualify those technologists who met the interim requirements as fulfilling the initial training and experience requirements of the final regulations. The final regulations also relax the requirements that had been proposed for training specific to imaging patients with implants and reduce the number of supervised examinations that have to be performed as part of the initial requirements and to ''requalify'' in cases where the continuing experience requirement has not been met. The following changes are discussed in connection with the specific provisions.

The general issue that drew the most comments was the question of whether a ''grand parenting'' clause should be added for presently practicing technologists.

(Comment 229). Over 30 comments urged that technologists who met the qualification requirements of the interim regulations should be deemed to meet those of the final regulations. An additional six comments urged that technologists who have earned the advanced certificate in mammography from the American Registry of Radiologic Technologists (the ARRT(M)) should be accepted as meeting the final regulations.

(Comment 230). Three comments recommended that either 40 hours of training or 20 hours and the ARRT(M) be the basis for grand parenting, while another comment urged that ''years of experience'' be the basis for grand parenting. Members of NMQAAC also recommended the addition of a limited grand parenting provision. Specifically, NMQAAC recommended limiting grand parenting to technologists who met the initial training requirements of the interim regulations by receiving 40 hours of training or earning the ARRT(M) (two of the several options that FDA had accepted under the interim regulations) and who had also performed at least 100 examinations.

Many comments expressed concern that, without grand parenting of present

technologists, there would be no one qualified to practice under the final regulations without more training. The comments asserted that these training demands would be expensive, disrupt facility routine, and overwhelm the training resources available to technologists. Some of the comments further argued that there would be no one qualified to provide this training.

The agency has been persuaded by the comments it received and the advice of NMQAAC that ''grand parenting'' provisions should be added to the technologist requirements. Under the final regulations technologists who have met the requirements of § 900.12(a)(2) of the interim regulations by the effective date of the final regulations will be considered to have met the initial mammography training and experience requirements in the new regulations. Section 900.12(a)(2)(ii) of the final regulations has been revised to reflect this. This change will achieve consistency with grand parenting provisions already existing for the other personnel groups. Although FDA believes that there are many technologists presently practicing who will meet the requirements of the final rule, this change will ensure that there will be an adequate number of qualified personnel to perform examinations and teach new technologists after the final regulations become effective.

FDA did not extend this grand parenting to the continuing education and experience requirements of § 900.12(a)(2)(iii) and (iv). Because these are ongoing requirements intended to ensure that technologists keep their skills sharp and their knowledge up-to-date, past qualifications can not be used to meet these requirements. Similarly, FDA did not include the general licensing or certification requirement established by § 900.12(a)(2)(i) as a qualification that could be grand parented. Because the license or certificate has to be renewed on a periodic basis, fulfilling this requirement in the past cannot justify exempting technologists from the need for future renewal.

On the other hand, FDA has declined to adopt the limitations on grand parenting proposed by NMQAAC. Under the interim regulations, FDA has accepted a number of ways for technologists to meet the initial mammography qualifications. Successful completion of 40 hours of training or the ARRT(M), the exclusive methods recommended by NMQAAC, are only two of these ways. Other ways technologists have been accepted as meeting the initial training requirement include obtaining a mammography certificate from the States of California, Arizona, and Nevada and successfully passing a comprehensive training course that is less than 40 hours in length but meets other rigorous criteria. Still other technologists have been accepted as qualified after a case-by-case evaluation of their qualifications. FDA estimates that as many as several thousand technologists might be disqualified if the NMQAAC recommendation was accepted, creating a potentially serious impact on access to mammography, and individual hardship. FDA has no evidence to indicate that these technologists as a group are performing inadequately and, therefore, has retained them within the scope of the grand parenting provision.

The requirements of § 900.12(a)(2)(i) are intended to provide some assurance that the radiologic technologist is qualified to perform radiologic examinations.

(Comment 231). Two comments supported this requirement as written, but others suggested various changes.

Over 20 comments stated that technologists should be required to be licensed in ''the'' State in which they were practicing or, at least, if they met § 900.12(a)(2)(i) through a State license, that it should be a license in ''the'' State of practice. A related comment suggested that FDA require technologists to meet State requirements that are as stringent as FDA's.

FDA has not accepted the suggestions made by these comments for a number of reasons. First, the statute provides that technologists be given a choice between State licensure or certification by a professional body (42 U.S.C. 263b(f)(1)(C)(i)) and the law also requires that the license be from a State, not ''the'' State of practice. FDA can not limit the choices established by the statute and notes, in addition, that some States do not have technologist licensure. FDA also believes it to be beyond the authority conferred upon it by the MQSA to stipulate State licensure requirements.

(Comment 232). One comment recommended that there should be national licensing of mammography technologists.

FDA does not believe that the MQSA contemplated the establishment of a national licensing requirement to replace State standards and procedures. The statute's specific reference to State licensing as an alternative requirement supports this conclusion (42 U.S.C. 263b(f)(1)(C)(i)(I)).

(Comment 233). With respect to certification, one comment urged that the general certification be limited by regulation to that of ARRT.

FDA agrees that ARRT general certification meets the requirements of § 900.12(a)(2)(I) and, in fact, this is presently the only certification accepted by the agency for this purpose. However, as discussed in the proposal, FDA does not want to codify a list of eligible certifying bodies because that will restrict its ability to add or delete organizations in a timely manner (See 61 FR 14900).

(Comment 234). Two comments suggested that FDA require certification bodies to establish a special mammography certification program based upon 6 months of training as an alternative to the general certification or licensing requirement.

FDA does not believe that this is necessary. Certification bodies are free to establish alternative programs and expand existing ones and FDA will evaluate such programs on a case by case basis. However, the increased level of training contemplated by this suggestion may not justify the cost. Similarly, although FDA believes that the suggestion in another comment that technologists be required to watch radiologists read films 8 hours every 6 months to improve ''rapport'' may be useful training, FDA has no evidence that the expected benefit would warrant mandating such a requirement.

The provisions of § 900.12(a)(2)(ii) are intended to provide some assurance that technologists possess adequate qualifications specific to mammography before beginning to perform mammography examinations.

(Comment 235). One issue related to these requirements drew several hundred comments, the largest number received on any part of the proposed regulations. This issue was the value of earning the ARRT(M) in meeting the specific mammography requirements for radiologic technologists. Unfortunately, over 80 percent of these comments, consisting primarily of multiple copies of 8 or 10 similar form letters, were based on a misunderstanding conveyed by an article in a journal that is widely distributed to mammography facilities. Many comments were based on an impression gained from this article that, because the ARRT(M) was not mentioned specifically in the regulations, it would have no weight in meeting the requirements. Some comments even indicated a belief that FDA would somehow ''take away'' the certification that the authors of the comments had worked so hard to obtain.

The authors of these comments unfortunately did not understand that the ARRT(M) has been given great weight under the interim regulations as

evidence that the technologist is adequately qualified, even though it is not mentioned explicitly in those regulations. In fact, none of the large number of certificates or training programs that FDA has accepted to meet part or all of the personnel training requirements are mentioned in the interim regulations. FDA, moreover, stressed in the proposed regulations that the agency has ''recognized the value of training hours required for ARRT special certification'' and intends to continue to do so (61 FR 14094). Specific mention of a credential in the regulations is not necessary for acceptance and, as discussed earlier, the agency has concluded that codifying particular organizations or programs will hamper the agency's ability to evaluate training programs on a case-by-case basis and to make timely changes in the acceptance of such training (61 FR 14900, 14904).

FDA regrets the distress this misunderstanding has caused many technologists and has contacted as many of the authors of these comments as possible to ease their concerns over the issue. The agency also has offered to work with the journal and the author of the article to ensure greater accuracy in future articles on the MQSA requirements. The journal has published the FDA correction of the article in an attempt to dispel this misunderstanding.

(Comment 236). Some of the comments received about the ARRT(M) made specific suggestions as to what type of recognition it should receive. Nearly 150 comments expressed the opinion that the ARRT(M) should be required of all technologists doing mammography, while over 40 more stated that it should be required in association with other training.

While FDA recognizes the great value of the ARRT(M) and intends to continue to accept it towards meeting the 40-hour requirement for radiologic technologists, the agency will not designate that particular certificate as a required or exclusive standard. FDA has no basis for establishing the ARRT(M) as the only way of demonstrating training in mammography. Furthermore, before a technologist can earn the ARRT(M), she or he must first earn general certification from the ARRT. The MQSA establishes that technologists have two alternative routes for general radiologic training: Either State licensure or certification by an approved professional group (42 U.S.C. 263b(f)(1)(C)(i)). If FDA were to require the ARRT(M), it would effectively eliminate the State licensure route to general qualification, in contradiction to the statuary provisions.

(Comment 237). Over 50 comments urged that the ARRT(M) be accepted as an alternative to the 40 hours of training required by § 900.12(a)(2)(ii). This also was the recommendation of NMQAAC members at the January 1997 meeting, although at earlier meetings NMQAAC had recommended that the ARRT(M) be accepted as equivalent to only 20 hours of training. One comment questioned the value of the ARRT(M), based on the opinion that the examination that must be passed to receive the ARRT(M) was not sufficiently specific to mammography.

FDA will not accept the ARRT(M) in lieu of the 40 hours of training required by § 900.12(a)(ii). The ARRT itself has recognized earning the ARRT(M) as equivalent to 24 hours of training. FDA does not have a basis for disagreeing with this evaluation by the sponsoring organization and, in most circumstances, intends to evaluate the ARRT(M) as equivalent to 24 training hours. FDA also notes that the performance of clinical examinations is a required component of the 40 hours of training required under § 900.12(a)(2)(ii) of the final rules. FDA has been informed by members of NMQAAC and others that technologists can and do pass the test for receiving the ARRT(M) without having performed any mammography examinations. For these reasons, although FDA did accept the ARRT(M) as meeting the interim regulation requirement to have training ''specific to mammography,'' and will continue to do so until the effective date of the final regulations, the ARRT(M) will not be considered equivalent to the final requirement of 40 hours of training, which must include the performance of examinations.

(Comment 238). Over 100 comments urged that the ARRT(M) be accepted as meeting at least part of the 40-hour training requirement of § 900.12(a)(2)(ii). Another 27 comments made suggestions for the number of hours for which it should be accepted, with the numbers varying from 5 to 30 hours.

FDA agrees that the ARRT(M) is acceptable for meeting part of the training requirement. Also, as already noted, the agency intends to accept the ARRT's estimate of the amount of training represented by its approved programs, unless there is evidence, now or in the future, that such acceptance is not warranted. Thus, the ARRT(M) ordinarily will be accepted as meeting 24 hours of the 40-hour training requirement and the agency reiterates that the fact that the ARRT(M) is not specifically mentioned in the regulations does not preclude this acceptance.

(Comment 239). A number of other comments addressed whether 40 hours of training was an adequate and appropriate amount to provide reasonable assurance of quality mammography. Twenty comments stated that it was a reasonable amount. Three comments asserted that the amount of training was excessive or even that training in mammography was not needed. An additional comment was concerned about the impact of the requirement on small facilities.

In response to these comments, the agency notes that training for radiologic technologists specific to mammography is required by the statute. The agency also notes that nearly all technologists who have met the interim regulations, whether at small or large facilities, have already obtained 40 hours of training or close to it without a noticeable adverse impact on the facilities. Some portion of these comments, and seven others, may have been based on the mistaken belief that the 40 hours was required to be in addition to any previous training in mammography. The grand parenting provision, which provides that meeting the interim regulations will qualify individuals as meeting the initial training requirements under the final regulations, should alleviate some of these concerns.

On the other hand, 14 comments stated that 40 hours of training was inadequate. Several of these made suggestions for higher levels of training, ranging up to 480 hours and including the performance of 200 examinations. The preponderance of the comments, however, seemed to support the figure of 40 hours of training. This amount was originally recommended, and is still supported, by NMQAAC. In the absence of any current evidence that 40 hours of training are insufficient, FDA believes that no change needs to be made in this number of hours.

(Comment 240). A number of comments addressed instructor qualifications. Concerns mentioned earlier, namely, that there would be no qualified instructors, have been addressed in part by the grand parenting provision. Thirteen other comments asked for more clarification as to who would be a qualified instructor or suggested listing specific categories of individuals who would be qualified.

FDA believes that the new definition of qualified instructor in § 900.2(oo) will address these concerns. Because of the wide variety of individuals who have expertise to provide the various segments of the technologist training, the agency wrote this definition with

the goal of describing certain groups that can be identified as qualified at this time, while retaining the flexibility to accept other individuals on a case-by-case basis.

(Comment 241). Three comments urged that the training be required to be Category A, but another comment said that such a requirement would make it difficult for a facility to find courses to qualify new technologists.

NMQAAC also did not reach a consensus on this issue. Although FDA has decided to accept only Category I training as meeting the interpreting physician requirements, the agency does not believe that a similar step is needed in the technologist area. In contrast to the situation with physician Category I and II training, the distinction between Category A and B is based upon whether or not prior approval by a recognized group has been obtained, not on the type of training. Thus, the concerns that led the agency to restrict physician training to Category I do not apply in the technologist situation.

Similarly, FDA does not believe that it is necessary to require the 40 hours of training to be ''graduate'' training that is taken after the technologist meets the requirements of § 900.12(a)(2)(i), as suggested by one comment. FDA is unaware of any reason to believe that the mammography training received as part of the technologist's basic training curriculum is unacceptable.

(Comment 242). Four comments were critical of the concept of continuing education courses, stating that students ''sleep through them'' and that they are only ''money-makers'' for the training providers.

While abuses of these types may exist, FDA believes that the great majority of training providers are sincerely interested in providing training that will improve medical care and that the great majority of students are equally interested in learning as much as possible from their training.

(Comment 243). Another large group of comments addressed the specific requirements included in § 900.12(a)(2)(ii). Nine comments suggested the addition of more subjects to those required to be included in the 40 hours of training. Specific suggestions included technical factors, film evaluation and critique, pathology, mammography of disabled women, and communication with patients. Three other comments supported the proposed inclusion of the topics of positioning and quality assurance.

FDA agrees that the topics suggested, and probably many others, could be valuable components of technologist training. Some, in fact, are subsumed under the topics proposed and finalized under § 900.12(a)(2)(ii)(A). However, the agency's intention was to limit this list in the regulation to only the subject areas most central to the quality performance of mammography examinations in order to maximize flexible and individualized training. FDA has added only imaging of patients with breast implants to the list of required topics, for reasons discussed below. The final regulation includes the words ''but not necessarily limited to'' to clarify that training in other areas also could be included in the 40 hours as long as the basic areas are covered. The agency intends to make additional information available on training programs and subjects that can satisfy this requirement.

At its January 1997 meeting, NMQAAC reconsidered a recommendation it made earlier and advised that FDA amend the proposed regulations to require the initial experience requirement of § 900.12(a)(2)(ii)(B) to be in addition to the 40 hours of training instead of part of the training, as was proposed. FDA did not receive any other comments making this recommendation. After considering the advice of NMQAAC, the agency has decided to retain the proposed requirement without amendment. FDA's experience in implementing the MQSA over the past years has not provided evidence that the significant increase in the training hours (approximately 50 percent over the proposal) that would result from NMQAAC's recommendation is warranted.

(Comment 244). Several other comments asked for clarification about whether previous training could be counted towards the mammography requirement or expressed concern about current technologists having to repeat their training. As explained previously, under the grand parenting provision that has been added, radiologic technologists who have previously qualified under the interim regulations will be deemed to have met the initial personnel requirements and will not have to repeat training for that purpose.

Section 900.12(a)(2)(ii)(B) requires that performance of clinical examinations under direct supervision of a qualified individual be part of the initial training. This requirement was intended to be parallel to the requirement that existed for interpreting physicians under the interim regulations and was continued for them in the final regulations.

(Comment 245). Eight comments supported this provision, noting that competency comes about by combining didactic training with actual experience and that such a requirement has worked well in the State of Iowa for several years.

A much larger number of comments opposed such a requirement. Eight of those opposing the requirement mistakenly believed that the supervision would have to be done by a radiologist and such supervision was not available in their situation.

Supervision of radiologic technologist examinations by a physician is not required; the new definition of a qualified instructor (§ 900.2(oo)) should help correct this misunderstanding.

(Comment 246). Twenty comments expressed concerns about having qualified supervision, especially in small and rural facilities. The new grand parenting provision that has been added to the final rule for radiologic technologists should solve this problem in areas where a shortage might have occurred.

(Comment 247). Nineteen other comments raised concerns about requiring supervised mammography examinations that related to issues of cost, liability, and patient privacy.

FDA notes that these are all issues that have been faced and successfully resolved by technologist schools nationwide in connection with the clinical training that they provide their students. FDA believes that they are manageable concerns and that any difficulties they raise are outweighed by the benefit of clinical training for radiologic technologists. The agency also notes that the addition of the grand parenting provision will limit this requirement to new technologists wishing to enter the field and that the number of examinations has been decreased, as discussed below.

(Comment 248). Six comments took the position that practical training was not needed. Their authors apparently believed that technologists could learn to adequately perform mammography examinations with only classroom training.

FDA disagrees. In view of the difficulty of performing adequate mammography examination, the agency believes that some clinical experience is vital for initial qualification.

(Comment 249). A number of comments expressed conflicting views on the appropriate number of examinations that should be done as part of the initial training. Twenty-two of these comments expressed the opinion that 50 examinations was too many, due to cost or difficulty of completing that number, or because of a belief that fewer examinations would serve the same purpose. Ten comments,

however, suggested higher numbers, ranging up to 200 examinations.

The question of the number of initial examinations was raised at the January 1997 NMQAAC meeting, but no recommendation was made on the issue. After considering these comments, FDA concluded that reducing the required number to 25 examinations would give the technologist adequate initial experience, while at the same time ease burdens relating to cost and availability of the training.

(Comment 250). A relatively large number of comments were also received on the requirements proposed in § 900.12(a)(2)(ii)(C). These comments focused primarily upon the proposal that all technologists doing mammography should receive at least 5 hours of training in the imaging of patients with breast implants as part of their 40 hours of initial training. Several different issues were brought up with respect to this requirement.

The first issue was whether it was at all necessary to require training in breast implant imaging. Over 30 comments supported this requirement. These comments noted that the training was necessary to perform adequate examinations of women with implants and that having the training would remove the need to have a physician present during the examination. About half of these comments recommended that no specific amount of training be required. Eighteen comments opposed any requirement relating to implant imaging, arguing that technologists were already obtaining such training as part of their initial curriculum, that imaging of women of breast implants did not require special training, and that their facilities conducted so few examinations that such a requirement would be ''overkill.''

A second issue was whether the training should be required of all technologists, as proposed, or just those who perform examinations of women with implants. One comment supported requiring it of all technologists in order to ensure that no matter what facility a woman with breast implants chose for an examination, she would be examined by a technologist with this training. The NMQAAC took this same position for the same reason. Ten other comments, however, urged that this requirement be limited in some way, with suggestions varying from limiting it to technologists who perform such examinations, to new technologists, or to technologists at facilities that perform a minimum number of examinations of patients with implants per year.

A third issue was whether there was sufficient training available in this area. Approximately 25 comments stated that there would not be sufficient training opportunities available to meet this requirement. A few of these comments supported this position with data from their own experience or surveys of training providers in their area. This position is in contrast with the comments mentioned earlier, which stated that this requirement was not needed because training of patients with breast implants was already routinely being received. The position is also somewhat inconsistent with the 15 comments FDA received from technologists who said that they had received the required training in the past, but might have difficulty providing documentation because their certificates do not specifically state the content of the training.

A fourth issue addressed in the comments was the proper mixture of classroom, video, and practical training. Eight comments stated that video training would have to be permitted because there would not be enough patients available to meet this requirement through clinical training. An additional 5 comments stated that it would probably not be possible to include clinical training. On the other hand, 20 comments emphasized the importance of clinical training and another 12 stated that it should be possible to receive this training in a clinical seminar. However, another comment pointed out that models would be reluctant to undergo the compression required by such training.

The final issue was the amount of training that should be required in imaging patients with implants. Nearly 30 comments expressed the opinion that 5 hours was too much for reasons that included cost and the belief that the necessary knowledge could be conveyed in less than 5 hours. Over 50 additional comments suggested specific and lesser amounts of training. About 80 percent of these comments supported a requirement for 2 hours of training, although some of those supporting 2 hours would also require an additional number of examinations under direct supervision. Several comments also suggested stating the requirement in a different way, for example, as part of a larger number of hours devoted to positioning or in terms of a minimum number of patients.

There were also a number of comments based on misunderstandings of the proposed requirement. Thirteen comments, for example, urged that the 5 hours be part of the general 40-hour training requirement, apparently not realizing that was already proposed. Seven other comments were based on the mistaken belief that implant imaging was a ''mammographic modality'' and that training in this area would also be required as part of their continuing education.

The training required for imaging patients with implants is part of, and not in addition to, the 40 hours of initial training and that the definition of mammography modality does not include breast implants. The agency expects to issue educational materials to help interpret the final regulations and will further clarify these and similar misunderstandings.

In response to the comments on the five major issues, FDA first notes that the statute requires the agency to establish standards relating to special techniques for mammography of patients with implants (42 U.S.C. 263b(f)(1)(H)). Requiring technologists to be trained in examining such patients is consistent with the statutory requirements. In addition, FDA has received many comments, including advice from NMQAAC, which underscore the necessity for performing such examinations with trained personnel.

The agency also notes that the grand parenting requirement will relieve technologists who met the interim regulations from the need to obtain additional training in the imaging of patients with breast implants. This should alleviate much of the concern that was expressed in comments about availability of training and the overloading of limited training resources. The grand parenting provision also eliminates the possibility that technologists who have been performing such examinations successfully for years but were not formally trained, or who do not have documentation of their training, would have to obtain this training. At the same time, all technologists newly entering the field will have to receive training in imaging of patients with breast implants. FDA believes this requirement strikes the proper balance to ensure that patients are properly examined.

Further, after consultation with NMQAAC, FDA concluded that this training should not be established as a separate requirement, but instead should be included under § 900.12(a)(2)(ii)(A) as one of the topics required to be covered during the 40 hours of training related to mammography. By including imaging of patients with breast implants among these required subjects, FDA ensures that all radiologic technologists being trained for the field of mammography will receive education in this important technique, as required by the MQSA. At

the same time, by eliminating any particular hourly requirement, the agency permits maximum flexibility in the amount and type of training received, plus some degree of assurance that the student will be evaluated in this area as part of the formal training process. Radiologic technologists who expect to examine patients with implants on a more frequent basis or facilities that have large numbers of such patients among their clients can increase the training hours in this subject. Conversely, radiologic technologists and facilities with few such examinations can devote training hours to other subjects that seem more beneficial to their practice, as long as the basics of imaging women with implants have been covered adequately. Because the hours devoted to such training are required to be documented contact hours under the supervision of a qualified instructor, a variety of types of training similar to those suggested in the comments could be suitable as long as they meet the criteria of § 900.12(a)(2)(ii)(A).

The second part of proposed § 900.12(a)(2)(ii)(C), which was that at least 8 of the 40 hours must be training with each mammographic modality used by the technologist, received far fewer comments.

(Comment 251). Five comments supported the requirement, although some concern about problems of documentation was expressed. Two comments opposed the requirement, one due to a mistaken impression about the number of modalities for which training would be required, the other because of a desire to leave the facility the flexibility to decide how much training was needed. Fourteen comments wanted the number of hours required per mammographic modality to be reduced.

FDA believes that much of the opposition to this requirement as proposed arises from a misunderstanding of what is meant by mammographic modality. Presently, there are only two mammographic modalities, screen-film and xeromammography, as defined in the regulations. Most technologists use only one or the other and, thus, this requirement has no great impact on them. For those technologists who do, or will, work with more than one mammographic modality, FDA does not believe it is excessive to have at least 20 percent of the total amount of initial training related to each mammographic modality used. Therefore, this part of the proposal has been retained in the final regulations.

The continuing education requirement, § 900.12(a)(2)(iii), was the first of two, along with continuing experience, intended to ensure that the technologists keep their skills and knowledge base up-to-date. The basic requirement proposed was that radiologic technologists have continuing education equivalent to 15 continuing education units in a 3-year period. The amount proposed was unchanged from that established under the interim regulations, but the proposed wording puts the emphasis on the total to be earned in a 3-year period instead of a yearly average.

(Comment 252). Five comments supported the requirement as being flexible and adequate to keep ''technologists on top of changes.'' Three comments opposed it on the grounds that the continuing education requirements of the ARRT were sufficient or that earning the ARRT(M) should excuse technologists from earning continuing education credits.

FDA is aware that the ARRT requires earning 12 credits per year while the proposed regulations require an average of only 15 per 3-year period. However, the 12 per year required by the ARRT continuing education standards can be from any area of radiology and will not necessarily be training in mammography. If the radiologic technologist takes mammography training to fulfill ongoing ARRT requirements, that training can be counted towards satisfaction of the MQSA continuing education standards. Similarly, while earning the ARRT(M) is evidence of a high level of knowledge at the time the test was taken, it does not ensure that the technologist will keep up with changes after that date, which is the primary purpose of continuing education. Thus, FDA cannot excuse technologists from this requirement on the basis that they have met the ARRT continuing education standard or have earned the ARRT(M).

Two additional comments supported the idea of looking back 3 years for the averaging period. Ten identical comments suggested changing the requirement to earning 10 hours every 2 years while two others urged that technologists be required to earn 5 hours of continuing education credit each year.

FDA established the longer time period for averaging continuing education credits to permit and encourage the technologists to take longer and more comprehensive courses as they became available. The agency believes such training may be more valuable than several short uncoordinated courses. Shortening the averaging period to 1 or 2 years would not prevent technologists from taking 15 credit courses, but it might discourage them from doing so due to a reluctance to pay for hours of training that would be beyond those necessary to meet the requirements. Use of a 3-year averaging period also provides greater flexibility in selecting courses that best meet individual needs and minimizes the possibility that a technologist will sign up for a course simply because it was available and the end of the year was approaching.

(Comment 253). Two comments urged that continuing education in implant imaging be specifically required as part of the continuing education for technologists.

In view of the many comments discussed earlier concerning the appropriate amount and type of training needed to successfully image patients with implants and the availability of that training, FDA has concluded that such a specific requirement would be too restrictive.

(Comment 254). A number of comments were received about the number of continuing education units being required. Eight comments asserted that the requirement of an average of 5 units per year would be too great a burden on technologists in rural facilities. On the other hand, one comment suggested increasing the number of credits required to 12 per year and provided further suggestions on the type of training, while another urged the requirement be raised to 10 credits per year.

After considering these comments, FDA has concluded that the 5 unit per year average is reasonable. Twelve units of continuing education per year are required to maintain the ARRT credentials and, at this time, the majority of radiologic technologists practicing mammography have ARRT certification. Because the 5 units required by these regulations can be part of those 12, the final regulation does not establish an excessive requirement. The agency also believes that, in association with the requirement in § 900.12(a)(2)(iii)(D) for extra training if the technologist begins working with a new mammographic modality, an average of 5 credits per year is adequate to ensure that the technologist keeps up-to-date.

(Comment 255). Five comments urged that only Category A training be accepted, while a sixth asked for clarification on that point and a seventh would restrict the training to certain types without reference to category.

For the reasons previously discussed, FDA does not believe that it is necessary

to restrict continuing education credits for radiologic technologists to Category A courses.

(Comment 256). One comment stated that a limit should be placed on the number of times credit could be earned for teaching the same course. NMQAAC, when discussing this issue, recommended that no credit should be given for teaching. FDA recognizes, however, that a great amount of study and learning is required to successfully teach a course, especially the first time it is given. The agency will continue to permit personnel to earn credit towards the continuing education requirement by teaching, but has added a new provision that limits the times a particular course can be counted towards this requirement to once in any 3-year period (see § 900.12(a)(2)(iii)(B)). This is consistent with similar provisions for interpreting physicians and medical physicists.

(Comment 257). A number of comments on this section were based on misunderstandings. One comment expressed the belief that this requirement actually meant that an individual would have to earn 15 units every 2 calendar years in order to meet this requirement. Another comment, incorrectly assuming that implant imaging was a mammographic modality, assumed that 6 hours of implant imaging training would be required every 3 years. Other comments mistakenly concluded that 5 credits on implant imaging would be required every year, that the requirement to average 5 credits a year was being increased to 6, or that 5 credits were being required each and every year.

All of these comments opposed the requirement based on their misunderstandings. As FDA develops educational materials to help personnel understand how they may comply with the new regulations, special attention will be focused on correcting such misunderstandings. Changes in the wording of § 900.12(a)(2)(iii)(A) from the proposal are intended to emphasize that the basic continuing education requirement is to earn 15 credits over 3 years and to clarify options for calculating the time period to be used to demonstrate compliance with that requirement. The agency hopes that these changes will eliminate confusion about whether 5 units must be averaged per year or earned per year (the unit requirement is an average) and provide radiologic technologists and the facilities that employ them with some flexibility in maintaining and documenting compliance with this requirement. Both of the changes parallel similar changes made in the wording to the interpreting physician and medical physicist requirements.

Only two comments were received on proposed § 900.12(a)(2)(iii)(B) (now § 900.12(a)(2)(iii)(C)), which requires a technologist to have some continuing education for all modalities used by that technologist. One comment stated this was a ''great revision.'' The other expressed concerns about the availability of the training.

FDA believes that if a new mammographic modality is introduced, training will be available initially from the originators of the mammographic modality because those originators will have a high interest in ensuring that the mammographic modality is used properly. FDA acknowledges that training with a disappearing mammographic modality, like xeromammography, may be more difficult to obtain. However, FDA has concluded that the possibility of detriment to the public health that could result from personnel not maintaining their skills must override this concern.

(Comment 258). FDA received four comments on proposed § 900.12(a)(2)(iii)(C) (now § 900.12(a)(2)(iii)(D)), which describes requalification procedures for technologists who failed to meet continuing education requirements. One comment agreed with the provision and two comments went further to suggest that there should be some sort of penalty for not meeting the requirement on time. The authors apparently did not realize that the penalty was not being able to perform mammography except under direct supervision until the requalification was completed (see previous discussion related to interpreting physician). The fourth comment supported the requirement, but expressed concern about who would approve the training and keep the records of completion.

FDA has found the mechanisms used under the interim regulations for approving training, which involve the participation of professional groups, are adequate. These same professional groups ordinarily provide documentation of completion. Under the interim regulations, it has been the responsibility of the facility to obtain and maintain such records and this will continue under the final regulations.

(Comment 259). The three comments received on proposed § 900.12(a)(2)(iii)(D) (now § 900.12(a)(2)(iii)(E)) opposed the requirement that a technologist receive training in use of a mammographic modality for which she was not previously trained before using that modality. One comment stated that the requirement would be an undue hardship and two stated that it will be difficult to obtain the training. FDA believes that the value of being trained in the use of a mammographic modality before beginning to use it on patients overrides the hardship concern. As discussed earlier, FDA also believes that availability of training will not be a problem and that the definition of qualified instructor (§ 900.2(oo)) provides for an adequate number of teachers. The proposed requirement has been retained unchanged.

Continuing experience is the second of the general requirements intended to ensure that the technologists maintain their skills. As proposed, § 900.12(a)(2)(iv) required that technologists perform a minimum of 100 examinations during a 12-month period. This requirement was intended to parallel the continuing experience requirement for physicians.

(Comment 260). Eight comments supported a continuing experience requirement for technologists, explaining that a technologist's positioning skills improve with additional mammography examinations. Nine comments opposed the requirement. Several of these suggested alternative measures, such as a ''lengthy appraisal (at least 3 days * * *) * * *'' by the chief technologist and radiologists or a certification program similar to that used by the American Heart Association for CPR certification.

While these suggestions have merit, they are a form of proficiency testing and, as discussed elsewhere, large numbers of comments provided valid reasons to conclude that it is premature to require such testing.

(Comment 261). Another comment opposed the requirement on the grounds that ''if you can do a mammogram, you can do it, period.'' The author's basic assumption seems to be that you never forget how to perform mammography. FDA notes that the purpose of continuing experience requirements is to ensure that technologist skills are maintained at a level that is likely to produce accurate and reliable mammograms. In view of the complexity of the examination and changes in technology, FDA believes that the optimism expressed by this last comment is unwarranted.

(Comment 262). Proposed § 900.12(a)(2)(iv)(A) set the continuing experience requirement at the performance of at least 100 mammography examinations in a 12-month period. One comment stated that this was a ''very acceptable requirement,'' but two believed that it

should be higher. One of these recommended that the number should be the same as the 480 interpretations a year required of radiologists. Four comments supported the level of the requirement, but asked that the averaging period be longer than a year to allow technologists to be absent for longer periods and still be able to meet the requirement. Two of these comments noted that physicians are allowed a 24-month averaging period for their continuing experience. Ten other comments suggested that the number be lowered, with 50 or 75 a year being the most common suggestions.

FDA has concluded that the number of 100 per year, which was first suggested by NMQAAC in February 1994, and supported by them at their January 1997 meeting, is the most reasonable compromise between the need to establish a requirement sufficiently high to maintain skills and the need to avoid disqualifying large numbers of competent technologists. The agency notes that as few as two examinations per week will be sufficient to meet this requirement.

FDA does agree with the suggestion that the averaging period be lengthened to 24 months and the wording of the regulation has been changed to require the performance of 200 examinations in a 24-month period. A clarification of how to determine the 24-month period was also added, which parallels similar provisions for calculating such time periods for interpreting physicians and medical physicists.

(Comment 262a). Seventeen comments identified specific groups that they believed would have difficulty meeting this requirement. These included individuals, such as mammography supervisors, instructors, and technologists in sales, who had made career choices that would make it difficult for them to meet this requirement.

FDA understands the desire of these individuals to keep their options open in case they wish to return to the performance of examinations, but the agency believes that higher priority must be given to maintaining technologist proficiency. FDA also notes, as discussed later, that a requalification procedure has been provided for technologists in this situation.

(Comment 263). A related concern was expressed in the 13 comments that indicated technologists in rural hospitals would have difficulty meeting this experience requirement. As explained previously, FDA recognizes that rural facilities face special challenges but believes that it would be contrary to the MQSA goal of assuring women a uniform minimum level of quality of mammography nationwide to establish lesser standards for technologists practicing in rural areas.

As proposed, § 900.12(a)(2)(iv)(B) stated that technologists who fail to meet the continuing experience requirement can re-establish this qualification through the performance of 50 mammography examinations under direct supervision.

(Comment 264). Ten comments stated that this number of examinations was too many and suggested that it be reduced, with 30, 25, and 20 examinations all being proposed. Another comment urged that there be a penalty for failing to meet this requirement, apparently not realizing that the penalty was not being able to work independently until requalification was completed. One comment urged that proficiency testing be used instead of an experience requirement, while another was concerned about how the performance of these examinations would be documented.

As discussed above, FDA has reduced the number of examinations that have to be performed under direct supervision as part of the initial training from 50 to 25. The agency has no reason to require the requalification figure to be higher than the number of examinations for initial qualification. Accordingly, the agency has similarly reduced the requalification requirement from 50 to 25 examinations.

d. *Medical physicist (§ 900.12(a)(3))*

Section 900.12(a)(3) establishes the requirements that must be met by medical physicists who conduct surveys of mammography facilities and provide oversight of the facility quality assurance program. Initial qualifications, alternative initial qualifications, continuing qualifications, and the reestablishment of qualifications are all covered. No major changes have been made in the final regulations from what was proposed. Some changes have been made in the survey experience requirement and in the averaging time for the continuing qualifications requirement. The comments received on the final regulations in each of these areas are discussed in below in connection with the specific provisions.

(Comment 265). One comment stated that the proposed rule is very positive, ensuring that only properly trained and adequately qualified professionals perform medical physics surveys. Another comment concluded that the medical physicist qualifications were appropriate and reasonable.

The initial qualification requirements for medical physicists include board certifications or State licensure or approval; masters degree or higher in physical science with 20 semester hours in college or graduate level physics; 20 contact hours of training in mammography; and survey experience.

The proposed initial qualifications requirements generated a wide spectrum of comments. Views varied greatly on the value of State approval or licensure in ensuring that physicists were properly qualified to perform mammography services.

(Comment 266). Ten comments expressed doubt that State approval/licensure provided a sound basis for establishing competence. One comment recommended that the State approval option be deleted, while another suggested that State approval be accepted only after FDA investigation. One comment stated that State approval/licensure should be part of alternative criteria with additional appropriate training and experience requirements. Three comments argued that State approval or licensure should be specific to the State where the professional practice will occur, unless a State reciprocity mechanism is in place. One comment stated that the proposal was unclear as to whether State approval was sufficient or additional requirements would need to be met after October 1997. On the other hand, seven comments stated that State approval, like board certification, was adequate by itself and that additional requirements were not needed.

Five comments stated that board certification should be required for all medical physicists. Several other comments urged FDA not to accept board certification without requiring a special certificate for mammography. Two comments recommended deleting the master's degree requirement and argued that course work in college level physics and supervised experience should be adequate. One comment contended that the issues of degree, training, and curricula are unnecessarily complicated in the proposed regulation. Another comment stated that the requirement of board certification or State licensure unfairly excludes physicists who are otherwise well qualified to test mammography equipment on the basis of their actual experience in this field. One comment stated that these requirements are appropriate.

FDA considered all of the comments received concerning initial qualifications requirements for medical physicists. Because the MQSA expressly establishes State approval or licensure

as an alternative pathway (42 U.S.C. 263b(f)(1)(E)(i)), FDA could not eliminate this route for initial qualification, even if the agency believed it was desirable to do so. The agency is aware that not all States have adequate minimum qualifications standards. Concern has also been expressed that some board certified physicists do not have adequate experience with mammography equipment. Therefore, as proposed, FDA added additional educational and experience requirements for all physicists, regardless of which initial route they follow to become qualified under the MQSA. These additional requirements are: (1) For initial qualification, masters degree or higher in physical science, with a minimum 20 semester hours or equivalent in college or graduate level physics, 20 contact hours of training in mammography, and experience of surveying 1 facility and 10 units; and (2) for alternative initial qualification, bachelors degree or higher in physical science, with a minimum 40 semester hours or equivalent in college or graduate level physics, 40 contact hours of training in mammography, and experience of surveying 1 facility and 20 units.

(Comment 267). A number of comments suggested that additional subjects, such as mathematics, biology, nuclear physics, and radiologic technology should be added as acceptable fields in which the degree may be obtained. Some comments wanted the reference to physical science to be changed to medical physics. One comment stated that physicists who are not board certified should be required to demonstrate a stronger educational background than currently required. In response to the agency's discussions in the preamble section of the proposal about the possibility of requiring all 20 semester hours in imaging physics (61 FR 14905), two comments stated that such a requirement would not be appropriate because the mammography equipment evaluation would require more than training in imaging and limiting 20 semester hours to imaging physics would not provide the physicist with the education needed to adapt to constant changes in technology.

The agency has decided to keep the requirement of physical science as the field in which the degree must be obtained and believes that its definition of physical science (§ 900.2(jj)) sufficiently covers the wide range of subfields that can provide adequate initial training to enable an individual with 20 semester hours of physics to understand the basics of mammography physics. The agency believes that this would not be the case if other fields, such as biology, were added to the definition.

(Comment 268). Sixteen comments stated that board-certified physicists should not have to demonstrate compliance with the additional educational requirements of § 900.12(a)(3)(i)(B)(*1*) in the proposed regulations, but should demonstrate experience conducting mammography surveys. Because the MQSA establishes board certification and State licensure/approval as equivalent pathways for qualifying medical physicists, FDA has not issued different additional qualifications for each of these groups. Accordingly, the agency has retained this requirement as proposed. However, if a designated board confirms that its certification in an accepted speciality always requires the minimum of a masters degree in physical science with at least 20 semester hours in physics, the agency may not have to verify the degree and semester hour requirements during annual inspections for those physicists certified by that board.

Another initial requirement is that physicists have 20 contact hours of documented training in mammography. Several comments requested further clarification of contact hours. Some comments urged FDA to accept self attestations of contact hours for experienced physicists who have worked in the field for a long time but do not have any documented contact hours. Ten comments stated that, if the medical physicist is board certified, the contact hours requirement should not apply.

After considering these comments and consulting with NMQAAC, FDA has retained contact hour requirements for all physicists, regardless of which initial route they followed to become qualified. FDA will accept self attestation of any contact hours received before October 1994. The agency has also provided a more detailed description of contact hours in § 900.2(m).

Under the proposal, an additional initial requirement was that medical physicists shall have the experience of surveying at least 5 facilities and 10 units.

(Comment 269). About one hundred comments opposed the requirement for multiple facility surveys for in-house physicists and stated that in-house physicists who are employed by hospitals and medical schools are often contractually prohibited from performing surveys at outside facilities. Several of these comments suggested that FDA should instead base its requirement on number of unit surveys.

In response to these comments, the agency has revised this requirement so that physicists qualified under § 900.12(a)(3)(I) will be required to have initial experience of one facility and ten unit surveys. FDA did not eliminate the facility requirement entirely because the agency strongly believes that having experience with complete surveys of facilities, including oversight of all QC records, is necessary. Evaluations of units only cannot provide a medical physicist with the same experience and knowledge as the survey of a facility. Although the amended regulation does not mandate survey experience with more than one facility, the agency encourages all physicists to perform additional facility surveys when possible to expand their experience. FDA believes that it is also advisable to gain familiarity with a number of different mammography units because much of the educational benefit is lost if the same unit is surveyed repeatedly to meet the experience requirement. In order to address this concern to some degree, the regulation now provides that no more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

The initial experience requirement also stated that, after the effective date of these regulations, the initial survey experience must be acquired under the direct supervision of a qualified medical physicist.

(Comment 270). One comment stated that direct supervision would be very difficult to arrange. Another suggested requiring two surveys under direct supervision and the rest under indirect supervision. The comment stated that indirect supervision with telephone consultation and advice is more valuable than the direct supervision.

FDA has retained this requirement because the agency and NMQAAC consider it important that new physicists entering the field acquire initial experience in conducting mammography surveys under the direct supervision of a qualified medical physicist, who can correct any mistakes made during the learning process before they pose to a threat to patients. Because this provision does not take effect until the effective date of the regulations, the agency believes that it will not disrupt the availability of experienced medical physicists.

Alternative initial qualifications were established in § 900.12(a)(3)(ii) to provide a way to permit medical physicists who have been successfully providing mammography physics services for some time, but who lack a masters degree, to continue to practice

without lowering quality standards in any manner that would jeopardize public health. In general, in order to qualify by this alternative qualification route, an individual must have qualified under § 900.12(a)(3) of the interim regulations and maintained his or her licensure, approval, or certification requirement as required under the interim regulations. The physicist using this alternative route is also required to have a bachelors degree or higher in physical science, with at least 10 semester hours or equivalent in college level physics, 40 contact hours of training in mammography, and survey experience of 10 facilities and 20 units.

(Comment 271). Several comments opposed the alternative pathway for initial qualifications and considered the proposed educational requirements for these medical physicists to be inadequate. On the other hand, a larger number of comments shared FDA's concern for existing medical physics service providers and the facilities they serve. These comments supported this alternative qualifications route and recommended that experienced individuals who have previously qualified and who meet continuing education and experience qualifications should be allowed to continue to practice. Five comments stated that the alternative initial qualifications should be a permanent option. One comment claimed that the proposed alternative qualifications criteria were too restrictive to permit many State licensed physicists to qualify.

A number of comments suggested increasing the requirement of semester hours of college level physics for this alternative route from the proposed number of 10. Some comments suggested that the credit hours requirement for this alternative route be increased from 10 to 15 or 20 hours by including subjects such as biology, radiation biology, radiation science, and chemistry. Other comments expressed concern that this college level physics requirement would bar a number of presently qualified physicists from continuing to provide mammography services. Two comments stated that the requirement for semester hours in physics should be removed, and that physicists qualified under the current interim regulations by the State licensure or approval process should not have to meet additional educational requirements. One comment stated that 10 hours of physics is reasonable. Another comment stressed that formal training in physical science is necessary and stated that this standard should not be weakened.

In the preamble to the final regulations, the agency explained its reasons for proposing the alternative initial qualifications route for physicists with bachelors degrees who are currently performing mammography physics services under the interim rule (62 FR 14905). Based upon discussions with NMQAAC and the Conference of Radiation Control Program Director's Task Force on Medical Physics Criteria, the agency proposed the requirements for course work in physics, contact hours, and experience included in this alternative route. The agency believes that the combination of all these requirements provides adequate protection for the public health, while permitting most practicing physicists to continue to provide mammography services under the final rule.

Moreover, the agency considered it to be unfair to individual physicists and potentially detrimental to facilities and the public to exclude many currently practicing physicists by withdrawing the alternative initial qualifications route or by increasing the educational credit hours requirement for these individuals in the absence of evidence that such physicists are providing inadequate services. The agency was concerned that such an exclusion could cause a possible shortage in the availability of physics services for some period of time.

Several comments supported the views expressed in the preamble to the proposed rule. In addition, the agency's experience and data gathered from its inspection data base affirm that many currently practicing medical physicists with bachelors degrees, adequate course work in physics, and substantial experience are performing quality medical physics surveys in mammography facilities with care and competence.

The agency continues to believe that it is very important to have at least 10 semester hours in college or graduate level physics. The other subjects, suggested by some comments, will not necessarily provide an individual with the necessary background and training to understand the basics of mammography physics. However, because at least a bachelors degree in physical science is also part of the educational requirement, the credit hours in other related subjects, suggested by the comments, may be associated with fulfilling the degree requirement. Although the agency believes that a minimum of 10 hours of course work in physics is necessary to gain proper physics background, it also believes that requiring more credit hours in physics, as some comments and some members of NMQAAC suggested, will exclude individuals other than physics minors or majors or those with graduate degrees. For these reasons and those previously stated in the proposed rule (61 FR 14905), the agency has retained, as proposed, the minimum requirement of a bachelors degree with no less than 10 semester hours or equivalent courses in physics in its final rule on alternative initial qualifications.

The agency agrees, however, that enhanced educational qualifications are necessary in order for physicists entering the field in the future to have the required background to understand the technology of the future as it becomes increasingly intricate. As previously proposed, therefore, FDA is limiting the use of this alternative pathway to only those physicists who have met its requirements by the effective date of the final regulations.

(Comment 272). Several comments opposed the contact hours requirement, while some supported it.

The agency has previously stated its justification for retaining this requirement for initial qualification route. For the same reason, the agency will retain the requirement for the alternative route.

(Comment 272a). A large number of comments stated that the proposed initial experience requirement of 10 facilities and 20 unit surveys for the alternative route in § 900.12(a)(3)(ii)(B)(*3*) would be impossible to achieve for many in-house physicists and suggested eliminating the reference to the number of facilities.

In order to be consistent with the initial requirements for physicists under § 900.12(a)(3)(i)(B)(*3*), the agency has revised § 900.12(a)(3)(ii)(B)(*3*) to change the required initial experience from conducting surveys of at least 10 mammography facilities and 20 units to conducting one facility and 20 unit surveys. Again, no more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

(Comment 272b). Two comments stated that the experience component under the alternative initial requirement should have to be fulfilled under the direct supervision of a qualified medical physicist, as required under § 900.12(a)(3)(i)(B)(*3*). Another comment suggested changing the effective date of this regulation to the effective date of this section because there is more than one effective date in these regulations.

The agency points out that § 900.12(a)(3)(i)(B)(*3*), which will take effect 18 months after these regulations

are published, will affect only new medical physicists entering the field. Because § 900.12(a)(3)(ii)(B) establishes that the alternative pathway is only available until the effective date of the final rules, the direct supervision requirement does not apply to the individuals qualified through the alternative pathway, because no one will enter the field through that pathway following the effective date of the rules. In response to the comments about varying effective dates in the proposed rule, FDA points out that, except for some of the equipment standards and equipment QC tests, all sections of the final rule will be effective 18 months after publication. This is clearly stated in the final rule.

The continuing qualifications requirements for medical physicists have two components: § 900.12(a)(3)(iii)(A) continuing education, which requires the physicist to earn 15 units over 3 years; and § 900.12(a)(3)(iii)(B) continuing experience, which requires the physicist to survey 2 facilities and 6 units over 24 months.

(Comment 273). One comment questioned FDA's authority to require continuing education at all.

In response, FDA observes that the MQSA is designed to provide the government with authority to issue and enforce standards to ensure safety and accuracy of mammography in the United States. The section of the statute relating to quality standards lists a variety of requirements for each group of personnel associated with mammography practice. Although only the requirements relating to interpreting physicians expressly includes a reference to continuing education, these requirements are not an exclusive or limited list of standards to be established by the agency. They represent only the minimum requirements that Congress mandated that the Secretary must ''include'' among those issued to ensure safety and effectiveness of mammography (42 U.S.C. 263b(f)(1)). Just as FDA has determined that continuing education is necessary to maintain the skills and expertise of radiological technologists, the agency has concluded that continuing education requirements are also essential for medical physicists, who play a critical role in guaranteeing the safe operation of equipment and effective quality assurance systems.

(Comment 274). One comment stated that these requirements are appropriate. Two comments asserted that self training by reading and studying should qualify. Other comments asked that continuing education units be better defined. Another comment stated that the language was too prescriptive. One comment stated that most medical physicists would have completed rather than taught continuing education units and another opposed giving repeated credit for a course taught several times. One comment maintained that no CME has been available for those who have tested Xerox systems for the last 5 years, and that such courses are unlikely to be available in the future.

FDA notes that the final rule establishes that the units earned through teaching of a specific course can only be counted once towards the 15 education units requirement. A new definition for continuing education unit or credit has been added in § 900.2(l). The agency will accept only the continuing education credits offered by professional organizations whose training is shown to be relevant and acceptable for medical physicists. Language clarifying the options for calculating the 3-year period has also been added. The agency understands that sufficient training opportunities may not be available in xeroxmammography. However, because only 0.5 percent or less of the facilities use xeromammography, the agency believes that the majority of physicists, if not all, will need only continuing education related to screen-film mammography. When other mammographic modalities, such as digital mammography, become available, medical physicists will need continuing education in those areas. The agency believes that such training will be increasingly more available as the technologies develop. The agency advises the facilities that use xeromammography to contact the manufacturer of this system to provide or arrange for training in xeromammography.

(Comment 275). One comment recommended that the second and subsequent 3-year periods begin to run from the original date that the physicist was required to meet the continuing experience qualification.

FDA decided to use a floating 3-year period for all mammography personnel, instead of a fixed 3-year period as suggested by the comment, for two reasons. First, as explained previously, a fixed period actually allows an individual to go much longer without continuing education than the length of the period itself. With a 3-year fixed period, for example, if an individual received training near the beginning of one period and near the end of the next period, he or she would go nearly 6 years without continuing education, which is entirely too long in a changing field such as mammography. Second, because inspections are annual, if an inspector found that an individual had not met the continuing education requirement during the previous fixed period, that individual might have provided services to the facility for almost a year before the failure was discovered. Depending upon the circumstances, the actions needed to correct the consequences of using the services of a noncompliant individual could require a considerable amount of time and money on the part of the facility.

(Comment 276). Two comments stated that persons providing continuing education should meet the qualifications of a medical physicist as described in the proposed regulations and that the instructors should be in active practice.

FDA disagrees. The agency believes that many scientists, university professors, and equipment manufacturers can provide training in different aspects of mammography physics.

(Comment 277). Another comment claimed that it is excessively bureaucratic to require that a physicist send a copy of his or her CME to include in the operating manuals, as was insisted upon by an inspector at their facility.

FDA believes that the author of the comment misunderstood the reason why the information on CME was required to be sent to the facility. The reason was not for inclusion in the facility's operating manual but to enable the facility to demonstrate that its medical physicist met the continuing education requirement. All interpreting physicians, radiologic technologists, and medical physicists providing services to mammography facilities have to document that they meet the continuing education requirement.

(Comment 278). One comment stated that there should be some penalty for failing to meet the continuing education requirements.

The consequences of failure to maintain these requirements is the inability to work independently as a medical physicist. As stated with respect to other mammography personnel, the agency believes this penalty is the most effective means to guarantee that physicists maintain qualifications and to protect the public health.

Under the proposal, FDA would require medical physicists to maintain their skills through the survey of at least 3 mammography facilities a year.

(Comment 279). More than 50 comments opposed this requirement. As

expressed in related comments, in-house physicists may be contractually prohibited from surveying outside facilities. Many of these comments suggested deleting the reference to the number of facilities.

In response to these comments and in order to establish consistency with revisions to the initial experience requirement discussed above, FDA has revised the proposed continuing experience requirement. The requirement will be for surveys of two facilities and six units in a 24-month period. The same facility can be surveyed twice. However, as with the initial experience requirement, no more than one evaluation of a specific unit within a period of 60 days may be counted towards the requirement. In addition, while the same facility may be surveyed twice within this 24-month period by an individual physicist in order to meet this requirement, the two surveys by this physicist must be at least 10 months apart. This restriction does not prohibit the facility from having surveys more frequently than once every 10 months, if it wishes to do so out of quality concerns or for other reasons. The restriction only limits the number of surveys of that facility that an individual physicist can use to meet his or her continuing experience requirement. The reduction in the number of facilities will address the concerns that were raised about in-house physicists.

In order to be consistent with the equivalent physician and technologist requirements, the continuing experience requirement for physicists is now based upon a 24-month period. This will now make it more feasible for physicists who are out of the field for a time, e.g., on maternity or sabbatical leave, to maintain their qualifications. The requirement has also been amended to explain options for identifying the 24 months that will be used to determine compliance. This change parallels similar changes in the requirements for radiological technologists and interpreting physicians and is intended to provide personnel and facilities with additional flexibility for monitoring compliance with these standards.

Section 900.12(a)(3)(iii)(C) requires physicists to be trained to do surveys of a mammographic modality for which they have not previously received training before independently doing surveys of such units.

(Comment 280). A number of comments correctly pointed out that the reference to mammographic ''examinations'' should actually be to mammographic ''surveys'' or ''evaluations.''

FDA has corrected this error by replacing the word examination with survey.

(Comment 281). Several comments opposed the requirement for 8 hours of training in a new mammographic modality prior to doing a survey of such a modality. One comment expressed concern that this will keep physicists from surveying new modalities. Another comment suggested that length and degree of training be commensurate with the specifics of the new modality. Two comments stated that the requirement overestimated the complexity of new modalities and undervalues the physicist's capability of adapting to new modalities in medical imaging. One comment stated that this rule is unnecessary because a qualified physicist will be able follow guidelines developed by ACR and AAPM when a new modality, such as digital mammography, begins to be used by the facilities. One comment stated that 8 hours of training in a nonscreen-film modality would be difficult to complete, while another comment stated that only expert instrument manufacturers would be qualified to provide such training.

The agency continues to believe that the proposed requirement of 8 hours of training in a new mammographic modality before a medical physicist may begin performing surveys independently in that type of modality is reasonable and necessary. Training prior to practice using a new mammographic modality is required for all critical personnel (interpreting physicians, radiologic technologists, and medical physicists) because FDA has determined that the benefits to patients from such prior training outweighs the cost to individuals and facilities. The agency recognizes that training in a new modality may not be widely available and agrees with comments that have observed that equipment manufacturers would and should be able provide such training. The agency will encourage manufacturers of a new mammographic modality, such as digital mammography, to provide or arrange for such training when the modality is commercially marketed.

Section 900.12(a)(3)(iv) describes measures medical physicists may take to reestablish their qualifications if they have failed to meet their continuing qualifications requirements.

(Comment 282). Two comments stated that the surveys of facilities and units required for reestablishing qualifications should be consistent with the experience requirement for initial qualifications. The authors believed that, if a medical physicist is not actively involved in mammography facility surveys for an extended period of time, performing the proposed three surveys may not be enough to regain the required expertise. They recommended that the requirement for requalifying be increased to five supervised surveys. One comment supported the qualification's supervision requirements. Another comment questioned why physicists are not allowed to perform surveys without the supervision of a qualified physicist, while such supervision is not required for physicians and technologists.

The agency notes that this provision has been amended to be consistent with similar provisions relating to physicians and technologists. In order to reestablish qualifications, physicists must perform facility and unit surveys to bring their total up to the required survey of 2 facilities and 6 units in the previous 2 years. This change also makes the requirements for continuing experience qualification more consistent with the experience requirements for initial qualification, as suggested by some comments. Any survey performed by a physicist to bring his or her total up to the requirement must be under the direct supervision of a qualified medical physicist. Contrary to the assumption in one of the comments, physicians and technologists who fail to meet their continuing experience requirement are also required to reestablish their qualifications under direct supervision and cannot resume working independently until the requalification is complete.

e. *Retention of personnel records (§ 900.12(a)(4))*

The provision on retention of personnel records § 900.12(a)(4) is intended to describe the personnel records that must be kept by the facility to establish that their personnel meet the MQSA requirements and to indicate how long such records should be kept.

(Comment 283). Ten comments disagreed with the proposal by FDA to allow records to be discarded following the next annual inspection and the resolution of any personnel problems discovered during that inspection. These comments urged that records be required to be kept for longer periods, with ''as long as the person is employed at the facility'' being the maximum suggestion. Four more comments suggested that FDA also establish requirements for how long records of staff members who have left the facility should be kept. One comment noted that the list of the people for whom records were required in the proposal included darkroom personnel and pointed out there were no specified qualifications for such individuals. Two

comments suggested that, if mammography is performed at various sites under the same ownership, the records be kept only at one site and be sent to the separate facilities as needed. Finally, one comment expressed the opinion that keeping personnel records was an unnecessary burden, but made no suggestions as to how personnel qualifications could be verified without documentation.

FDA has made a number of changes in this requirement in response to the comments. First, to address the concern about inclusion of darkroom personnel, the list of activities performed at a facility has been replaced with a reference to those personnel for whom quality standards have been issued. The wording was further changed to clarify that, as long as an individual is employed at a facility in one of these capacities, records must be available to show that the individual meets all qualifications. Records for individuals who have left the facility may be discarded after the next inspection has occurred and FDA has determined if the individual met the requirements. Although nothing in the MQSA or these final regulations precludes the facility from retaining these records for longer periods of time, FDA does not expect to have further need to review such records following the subsequent inspection. In response to comments suggesting that multi-site facilities retain personnel records in a central location, FDA notes that such a practice would be permitted but is not required under the final rule. Because the MQSA inspections are typically announced in advance, a facility could store its records at one site and bring them to the other sites as needed for review during the inspections there.

2. Equipment (§ 900.12(b))

The requirements were intended to establish specifications to ensure that each facility would have equipment that is capable of producing quality mammograms. FDA made a number of significant changes in the equipment requirements that were proposed. These changes include removing several of the requirements proposed for phase-in 5 and 10 years after the publication of the final rule and moving several requirements from § 900.12(b) to the quality assurance paragraph in § 900.12(e). Most of the test procedures that would have been required under the proposal have also been deleted. Each of these changes will be discussed below.

a. *General comments on equipment*

(Comment 284). A number of comments raised issues that did not address specific provisions proposed under § 900.12(b), but were directed generally toward the entire package of regulations governing equipment. These included two comments that expressed a blanket support for the regulations proposed under § 900.12(b).

One comment stated that it would be useful to have a better delineation of responsibility for ensuring that units meet particular standards under the MQSA. The comment recommended that the facility medical physicist be designated as the individual responsible to ensure that a facility's equipment is in compliance.

FDA believes responsibility for compliance with all the MQSA requirements rests ultimately with the facility. Within the scope of each facility's individual operations, responsibility can be apportioned as the facility wishes, so long as this is consistent with the regulations. The suggestion made by the comment is not inconsistent with the regulations. Under § 900.12(d)(1)(iv), the medical physicist is designated as the individual responsible to oversee the QC requirements, though no provisions specifically require routine QC testing to be performed by the medical physicist.

(Comment 285). Three comments suggested that FDA cannot anticipate future changes in mammographic equipment technology sufficiently well to be able to determine all appropriate requirements in this area over this extended timeframe. One of these recommended that FDA review the equipment requirements on a continuing basis to recommend and propose modifications that are recognized to promote quality mammography. One comment suggested that FDA simply require all mammography X-ray units to be replaced every 8 to 10 years in order to keep facilities upgraded with standardized equipment.

FDA agrees that it cannot anticipate all changes in mammography equipment over the next 10 years and has not attempted to do so. In the proposed regulations, FDA simply incorporated specifications of current equipment that experts had deemed desirable for quality mammography systems. The goal of the proposal was to ensure that, 10 years in the future, each facility would be using equipment that was considered state-of-the-art in today's market. FDA approached this goal by phasing-in the requirements over various time periods. Equipment requirements considered most fundamental to the delivery of quality mammography would be required first, followed by those specifications considered useful but which, because of cost impact, could be delayed for a period of 5 years. The third phase under the proposal included ''nice to have'' features that are not absolutely necessary to the production of quality mammograms and would not be required until the end of a 10-year period. However, based on the uncertainty surrounding the need for the phase three requirements, consultation with NMQAAC and industry representatives, assessment of the costs associated with some of the proposed 5-year phase-in requirements, and consideration of the public comments, FDA has determined that this goal is inconsistent with efforts to keep the costs associated with the delivery of mammography services at a manageable level. The agency has, therefore, decided to eliminate many of the requirements that had been proposed for both 5- and 10-year phase-in. FDA has previously stated that it plans to periodically review the regulations for necessary revisions in response to new technology and remains committed to that effort. The agency intends to and will revisit these areas in the future to reassess the need for additional regulations.

Although the revised equipment standards do not mandate that each facility have all the equipment features the agency originally had proposed, FDA believes the final regulations establish basic requirements that ensure that every facility meets the baseline equipment standards necessary to perform safe and accurate mammography. In response to the comment that recommended requiring new equipment every 8 to 10 years, FDA does not believe that the costs associated with the arbitrary replacement of mammography equipment every 8 years to 10 years is justifiable. In addition, the agency notes, too, that the alternate standards provisions, included in the regulations under § 900.18, provide the flexibility needed to ensure that new and innovative advancements reach the market without unnecessary delay.

(Comment 286). Two comments recommended that all detailed testing procedures be eliminated from § 900.12(b) to allow flexibility for qualified medical physicists to determine the appropriate testing methodology.

FDA has, in large part, adopted this approach in the final regulations. In doing so, the agency has placed responsibility on the medical physicists to be able to justify the procedures that they utilize to perform testing of equipment in any particular facility.

(Comment 287). One comment suggested that the X-ray tube companies are ''planning for early tube retirement so they can replace the tubes frequently at high cost to the facilities.'' The comment asked FDA to address this issue immediately in an effort to keep mammography costs down.

FDA does not control the pricing of equipment in the marketplace. The agency is, however, interested in equipment problems that may indicate a unit does not meet its specifications and/or aspects of compliance that it is certified as meeting. Specific information about manufacturers should be submitted to the Office of Compliance in FDA's Center for Devices and Radiological Health, 2094 Gaither Rd., Rockville, MD 20850.

(Comment 288). One comment suggested that there should be a lock-out and/or alarm mechanism preventing a mammography technologist from exposing the patient to radiation without placing film in the equipment. Another comment suggested a requirement for an interlock to prevent a second exposure until the cassette is changed, and two more comments recommended a requirement for an interlock to ensure the presence of a cassette in the bucky/film holder. These comments noted that such incidents have occurred, needlessly exposing patients to radiation multiple times because the technologist forgot to insert or change the film.

Although FDA is aware that some manufacturers include interlocks that ensure the presence of a cassette or that cassettes are changed after each exposure on their equipment, FDA is not considering such requirements at this time. FDA believes that, unlike equipment performance, this is an aspect of the mammography process that is within the complete control of the technologist and that the technologist must assume responsibility for preparing the system for each exposure. In facilities where more than one technologist uses the equipment, a check list of items should be followed and this should most certainly be one of the items on the list. If the technologists adequately follow standard procedures, incidents such as those described in the comments can be prevented without incurring the considerable expense involved in requiring the suggested interlocks.

(Comment 289). One comment asked the agency to consider requiring special grounding devices to protect operators and patients. The comment also suggested a prohibition against carpeting in the mammography room, and a requirement for the use of static mats around the mammography machine.

Although these items might be desirable they do not impact the quality of the mammography image and are beyond the scope of these regulations.

(Comment 290). One comment suggested that a requirement establishing a maximum distance from the surface of the patient support to the sensitive part of the image receptor should be incorporated in § 900.12(b).

FDA is not aware, and the comment did not offer evidence to show, that this represents a problem for current mammography systems. Accordingly, the agency is not planning to regulate this aspect of equipment performance.

(Comment 291). One comment suggested that the maximum allowable photo-timed exposure for mammography applications should be specified. The comment stated that the backup limit of 2,000 mA's (from 21 CFR 1020.31(a)(3)(iii) in the *Performance Standards for Diagnostic X-ray systems and their major components*) was clearly selected based on prior technology, i.e., much slower screen-film systems or, perhaps, industrial X-ray film where exposures were typically on the order of 5,000 milli Roentgen (mR) for an average breast.

FDA notes that the regulations under 21 CFR 1020.31 presently set a limit of 2,000 mA's for automatic exposure control equipment when operating with a peak tube potential under 51 kVp. This regulation is not specific to mammography, but applies to any diagnostic X-ray equipment operating with a peak tube potential under 51 kVp. In previous draft regulations presented to NMQAAC, a lower value of 600 mA's was proposed for mammography systems. The committee was of the opinion that 600 mA's was too low and FDA planned to increase the value to 800 mA's. In the meantime, FDA received comments from industry pointing out that some systems have variable SID capability. This variability in current equipment undermines an approach that relies on the maximum mA's concept because the mA's required at a longer SID may be significantly greater than that required at a shorter SID, although the dose delivered might remain constant. Because FDA was faced with setting dose limits for the termination of the exposure or unnecessarily limiting equipment SID, the agency decided that the maximum allowable photo-timed exposure should not be prescribed in the regulations at this time. This decision was presented to NMQAAC, which had no comment. FDA may revisit this area in future proposals.

(Comment 292). One comment noted that the time between exposure of the film and photographic processing is critical because the latent image on all film decays with time.

FDA had considered this aspect of the imaging process for regulation but, based on comments from the public and NMQAAC, decided not to propose requirements at this time. This area may be revisited in the future when more is understood about the requirements and practices in the mobile mammography community, where film processing often must be delayed for a significant period of time after exposure.

(Comment 293). Several comments recommended that FDA set standards for batch variability of film, stating that this variability is often greater than that proposed for the equipment standards.

FDA recognizes that the variability of film may be a potential problem but believes that facilities can control this, to a significant degree, through their purchasing specifications and selection of suppliers. FDA will monitor this problem closely to determine if future regulation is required.

(Comment 294). Twenty-five comments recommended that FDA include requirements for the viewbox and/or the viewing conditions for the physician and technologist.

FDA agrees such standards would be beneficial, but does not believe that enough is known, at this time, to set appropriate specifications for viewing conditions. The guidelines recommended by ACR are excellent and the agency encourages facilities to follow them. FDA will consider this subject for future regulation and all relevant comments will be reconsidered at that time.

(Comment 295). Thirty-nine comments expressed concern that the cost of some or all of the equipment regulations would cause facilities to close and thereby restrict access for patients. Many of these comments urged that the equipment requirements should be made to apply to manufacturers of equipment for items manufactured after the specified effective date of the regulations. A related comment suggested that the current interim rule, which requires only that equipment be specifically designed for mammography, is working well and that further regulation proposed under § 900.12(b) will serve only to stifle invention, add cost, and ''overly rigidify'' this important aspect of providing the highest quality mammography services at the lowest cost to the public.

FDA can understand why the last comment believes the interim regulations are far less extensive than what was proposed. The interim regulations address the equipment aspect of mammography quality directly by listing four criteria that all X-ray systems used for mammography must satisfy: (1) The X-ray equipment must be specifically designed for mammography; (2) it must be certified to meet the performance standards in 21 CFR 1020.30; (3) it must have a removable grid; and (4) it must have a compression device. In addition, however, the interim regulations required each facility to undergo an annual survey in accordance with the standards specified in the 1992 or 1994 ACR QC manuals (see § 900.12(d) and (e) of the interim regulations). These manuals outline extensive requirements for the equipment associated with the mammography process. In the final regulations, FDA has not referenced these manuals although NMQAAC strongly advised their continued use and has instead included specific requirements that were part of the ACR standards under final regulations at § 900.12(b) and (e). Although they appear as new regulations, many of these new provisions merely restate requirements that previously had been referenced through the ACR manuals but are now reformatted as regulation.

FDA is also concerned about all costs associated with the regulations under the MQSA, including those incurred by the purchase, upgrade, and repair of equipment. However, FDA's authority under the MQSA relates to the user of the equipment rather than the manufacturer. Under authority granted to FDA by provisions of the act (which incorporates the Radiation Control for Health and Safety Act of 1968), FDA is pursuing a parallel path to generate standards for new equipment under § 1020.30. This process will take some time and regulations on new equipment only gradually affect the installed base. The agency concluded that regulations directed at new equipment only, and not the installed base, would have inappropriately delayed the benefits of the improvements provided by the new equipment for millions of women for a number of years.

For these reasons, FDA determined that equipment standards implementing the MQSA should be directed to the installed base to ensure that all women, not just those that utilize facilities with new equipment, receive an adequate and equal baseline of care. Based on facility inspection experience with the interim regulations, FDA does not expect a large reduction in providers and anticipates no access problems solely as a result of the equipment regulations. In addition, FDA has provided mechanisms for alternate standards in § 900.18 to allow for innovation and flexibility under the final rule. The agency has no reason to believe that the regulations will cause stagnation in the market for new and useful equipment.

(Comment 296). One comment asked if it was necessary to attempt to codify and regulate equipment standards that, in the respondent's opinion, will evolve anyway through competition in the market.

Again, the agency responds that the introduction of new products into the market place can be a slow process and waiting for manufacturers to manufacture and market and for users to purchase would not produce the change in minimum national standards that FDA perceives is needed. Additionally, in FDA's experience, certain segments of any market are often driven by price concerns rather than features or performance. FDA believes that regulations are the only mechanism that will provide the impetus to achieve the desired baseline of care in a reasonable time.

(Comment 297). One comment supported phasing in the equipment standards over the next 1 to 10 years, as discussed in the preamble to the proposal (61 FR 14909). Two comments stated that 5 years is not a sufficient amount of time to require the purchasing of new equipment and maintained that it would be more appropriate to allow a longer phase-in period, for example, 10 years.

Five comments offered a contrary point of view, suggesting that the majority of the mammography equipment presently in use meets most of the proposed standards in § 900.12(b) and that many of the timeframes proposed in § 900.12(b) are excessively long. One of these comments expressed concern that there are some facilities where the machine limits the ability to do adequate imaging and the facility will not get newer equipment if not forced by law to do so.

FDA appreciates these comments and recognizes that some facilities will not upgrade their equipment until the last possible moment, thereby using equipment that has become inadequate by current standards. The agency must balance these concerns with cost concerns that facilities, patients, and FDA all share. The decision to require certain equipment standards to be phased in relatively quickly and postpone others represents the agency's efforts to balance these competing concerns.

(Comment 298). One comment suggested that there should be regulations for needle biopsy systems in § 900.12, including provisions that address misalignment of the biopsy cross-hair. The comment stated that the cross-hair assembly, if not accurately aligned, may lead to inaccurate localization of lesions during needle localization, increasing the possibility of morbidity. FDA recognizes the need for regulation in this area and has raised the issue with NMQAAC in the past. As a result of discussions with NMQAAC and opinions offered by the ACR, the decision was made to delay regulations for this aspect of breast radiography until community consensus can be reached on all aspects of the process. As discussed earlier, FDA is currently working internally on possible regulations for interventional mammography, while awaiting the results of collaborative efforts between the ACR and the American College of Surgeons to reach consensus on recommendations for standards in this area.

(Comment 299). One comment recommended that the equipment specifications proposed under § 900.12(b) should not be included in the final regulations and that the entire section should be issued as guidance rather than a binding regulation.

FDA has considered this approach, but has determined that, because the guidelines would not have the force of law, they would not achieve the widespread results necessary to meet the goals of the MQSA.

(Comment 300). Nine comments expressed concern that the proposed regulations under § 900.12(b) were not specific as to whether all equipment in a facility must comply and one of these comments questioned if existing mammography units must be redesigned and/or upgraded to all the standards by the effective dates.

FDA intends that all facilities performing mammography shall meet each of the final regulations by the effective date of each requirement. In the case of equipment, all equipment used for covered mammography procedures must meet the requirements in effect at any given time. If equipment must be repaired, replaced, or upgraded to achieve this result, then such actions must be completed by the effective date or the facility must discontinue offering mammography services with the nonconforming equipment until compliance is achieved.

(Comment 301). One comment stated that the equipment standards sometimes

give very specific descriptions of testing equipment and procedures. For example, in proposed § 900.12(b)(4)(iv), FDA specifically described a 12 cm diameter acrylic disc 1.5 cm thick. The respondent was unsure why 12 cm was specified instead of 10, and why 1.5 cm was specified instead of 1 or 2.

FDA notes that in each case where test procedures and/or test objects are specified in these final regulations, the objects or procedures are usually based on established test protocols. In some cases where the test object itself could be variable, the specifications are identical to an object used in another required test in order to reduce the number of items required for the entire survey or inspection. In cases where the test or the test object is new, the details of its design are beyond the scope of this document. FDA intends, whenever possible, to issue guidance documents that will address the use of such new procedures and equipment. The particular example cited in the comment has been deleted from the final regulations.

(Comment 302). One comment stated that the proposed rules are not entirely consistent with the guidance document developed by ACR and CDC. The comment recommended that every effort should be made to ensure consistency with the ACR guidance document.

FDA is, of course, aware of the ACR/CDC document and, in fact, adopted many of its requirements for these final regulations. However, the ACR/CDC document was written as a guideline for new equipment and not as a regulation for installed equipment. As a guideline, its wording would not readily transfer to regulation and, as a specification for new equipment, its scope was not sufficiently broad to address the range of the installed base or the cost concerns associated with upgrade and replacement of equipment. The agency also notes that the recommendations in the ACR/CDC guidance represent an attempt to describe an optimal system. NMQAAC and members of the public have stated that some of the features, while desirable, would generate costs not justified by the expected benefit, especially when applied to the installed base. In those cases where the agency believes the benefit does not warrant the cost, FDA has not made particular features regulatory requirements. Within these limitations, FDA has generally made efforts to remain consistent with the ACR/CDC guidance where doing so is appropriate.

(Comment 303). One comment suggested that a section in § 900.12(b) or (e) should address the issue of screen placement in the cassette. The comment noted that, because the screen is sometimes not positioned with its edge in contact with the inside wall of the cassette at the chest wall, the film edge is underexposed or unexposed. The comment suggested that ''such cassettes should be rejected and the screens remounted.''

FDA agrees that such conditions should not exist, but believes the annual survey and normal QC procedures will identify and correct such problems and is not considering regulations to address this concern at this time.

(Comment 304). One comment recommended that the proposed equipment regulations in § 900.12(b) be rewritten to correspond more closely with existing international standards.

In certain aspects of equipment related requirements, FDA has attempted to conform to both national and international precedent. However, in some cases, those guidelines are inappropriate or do not address the specific concern being considered under the MQSA.

(Comment 305). One comment suggested that the proposed requirements of § 900.12(b)(17) through (21), which do not relate to X-ray equipment or film processors, should be included as part of the annual physics survey and need not be specified by regulation. FDA believes that this respondent misunderstood these provisions because the core of the annual physics survey is, in fact, set forth in these regulations. Some of these regulations have been modified and/or transferred to the quality assurance section of the final regulations, while others have been deleted. The remaining requirements may be checked as survey or inspection items, verified by documentation provided by the manufacturers, or established through normal QC procedures performed by the facility. Although the agency has not expressly prescribed how these requirements should be met in all cases, FDA has determined that the facility is responsible for establishing compliance with these standards rather than trusting that they would be included in all medical physicists routine surveys.

b. *Prohibited equipment (§ 900.12(b)(1))*

This paragraph prohibited the use for mammography of general purpose equipment or equipment designed for special nonmammography procedures.

(Comment 306). Seven respondents recommended that the use of xeromammographic equipment should be prohibited or phased out.

FDA considered taking this action but believes that the unique characteristics of the xeroradiographic process may provide a valuable tool in the diagnosis of some cases. Records obtained during the first year of facility inspections under the interim regulations indicate that there are an extremely small number of these units in service and it is believed that the number will continue to decrease as their use falls out of favor with the community. FDA has concluded, therefore, not to ban their use.

c. *General (§ 900.12(b)(2))*

This paragraph, as proposed, required that all equipment be designed for mammography and certified under § 1020.30.

(Comment 307). One respondent suggested that a definition of ''specifically designed for mammography'' be included because some units may be used for imaging of extremities.

FDA does not believe that this is necessary because the manufacturer's labeling, along with the FDA device approval process, ensures that the design is appropriate for mammography. FDA recognizes the fact that the characteristics of mammography radiographic equipment make it useful for other radiological examinations and does not intend to restrict such applications if the product has also been approved for that use.

d. *Motion of the tube-image receptor assembly (§ 900.12(b)(3))*

This paragraph proposed that the gantry be capable of specific rotation, that the angle of the gantry be indicated, and that the tube-image receptor assembly remain rigidly fixed in any position where it was designed to operate.

(Comment 308). Two comments noted a citation error in the proposed regulations. One comment recommended the deletion of the entire section, with the possible exception of requiring the system to remain fixed when placed in an operating position. Three other comments supported the proposed requirements, although one suggested that only one unit at each facility need meet the requirements. NMQAAC supported the proposed requirements, with the recommendation that they be applicable only to equipment acquired 5 or more years after the publication of the final regulations.

FDA has determined that NMQAAC's recommendation to require compliance only on equipment acquired 5 or more years after publication of the final regulations presents major problems with respect to enforcement. Such an approach would produce a situation where two distinct levels of quality would be in place for different facilities

and often within the same facility, based on when equipment was acquired. After reviewing the public comments and assessing the possible cost impact of the requirements, FDA decided to remove the provisions detailing the range of gantry motion and angle indication. If this area is considered for future regulation, all comments submitted on these sections will be reconsidered in the process. FDA has reworded the provision that requires the tube-image receptor assembly to remain fixed in its designed operating positions and this requirement remains under § 900.12(b)(3) in the final regulations. The citation error has been corrected.

e. *Image receptor sizes (§ 900.12(b)(4))*

This paragraph requires that all mammography systems have, at a minimum, both a 18 X 24 cm and 24 X 30 cm screen-film receptor and matching grids, and that the grids should be removable. This section also proposed that grid motion should not be impeded when a breast is subjected to compression in the system.

(Comment 309). Seven comments supported the proposal regarding the image receptor sizes and matching grid requirements proposed in § 900.12(b)(4)(i). Two comments opposed the specification requiring both a large and a small image receptor system in the regulations. One of these misread the proposal as being applicable to xeromammographic equipment and suggested that the regulation might prohibit the use of such equipment because such systems may not provide multiple image receptor sizes. The other comment supported the concept of requiring a large and small image receptor combination, but opposed a provision specifying the actual dimensions of these receptors. A related comment, while not actually opposing the proposal, expressed concern that requiring multiple image receptor sizes for screen-film systems might establish difficult precedents for future technology.

FDA believes that, for the present and foreseeable future, the dominant film sizes used in screen-film mammography will remain 18 X 24 and 24 X 30 cm and has not been persuaded to revise the provision that requires systems to have both sizes with corresponding grids. The agency believes that the last comment is concerned with digital systems currently under development and the concern that large or multiple sized image receptors would be prohibitively expensive with such systems. FDA has not formulated an opinion in this area and will wait to see what final technology and configurations evolve for digital systems before addressing this issue in regulation.

(Comment 310). One comment, while neither agreeing nor disagreeing with the requirement for multiple size image receptors, stated that the use of smaller image receptors, even on large breasts, results in clearer, sharper images and noted that larger areas compressed all at once do not provide the sharpness and detail needed to pick up very small cancers. The comment stated that, even though more films are taken when a smaller film size is used to image a large breast, the benefits of finding a life-threatening cancer far outweigh the minimal increase in radiation exposure to the patient.

FDA recognizes this practice as essentially the ''spot compression'' of the entire breast in multiple exposures. Although ''spot compression'' can yield improved images, it is not a recognized or accepted procedure in screening mammography. Interpreting physicians who deem such studies necessary will order them to be performed, but it is not standard practice for routine screening. The agency also notes that the regulation merely requires that the two-image receptor sizes be available; their use in any particular case is left to the judgment of the mammography personnel involved.

(Comment 311). One comment proposed that the requirement for multiple image receptor sizes be restated to require at least one unit at the facility to provide the multiple sizes, rather than requiring each unit to have both receptors. Experts on NMQAAC recommended that the requirements of § 900.12(b)(4)(i) not be weakened by permitting a facility to satisfy this equipment standard by having only one system with the multiple cassette sizes. The rest of the committee agreed. FDA has accepted this advice and retained this requirement under § 900.12(b)(4)(i).

Section 900.12(b)(4)(ii) requires facilities to have systems with moving grids matched to all image receptor sizes provided.

(Comment 312). One comment commended FDA for requiring both an 18 x 24 and a 24 x 30 bucky for each unit. Another recommended that the regulation read: ''Systems using screen-film image receptors shall be equipped with separate moving grids matched to all image receptor sizes provided.'' FDA does not believe that the suggestion was a significant improvement and did not make the change.

(Comment 313). One comment recommended the inclusion of a requirement in § 900.12(b) that specifies the image receptor support device shall match the cassette size.

The agency does not believe this additional requirement is necessary. By requiring the system to have both a large and small image receptor and corresponding sized grid assemblies, FDA is confident that most technologists will select the appropriate receptor and cassette size for each patient.

Section 900.12(b)(4)(iii) requires the grid to be removable for systems used for magnification.

(Comment 314). Three comments requested clarification regarding applicability and intent of this provision.

FDA notes that the final regulation was drafted to clarify the interim rule. Section 900.12(b)(4)(iii) simply states that the system must be operable with the grid removed from between the source and the image receptor when the technologist is performing magnification procedures. This could be accomplished in various ways, including actually removing the grid mechanism, substituting a nongrid film holder for the grid film holder assembly, or any other mechanism that ensures that the grid does not interfere with the image or the automatic exposure control, if one is used.

Under § 900.12(b)(4)(iv), FDA proposed that the grid motion not be impeded when the breast is compressed and also proposed detailed requirements for verifying compliance.

(Comment 315). Seven comments supported the proposed requirements for assessment of grid related artifacts, while 14 comments supported the concept of evaluating grid related artifacts, but opposed both listing the requirement in regulation and the test procedure outlined in the proposal on the basis that the test method was unproven and objective standards for evaluation of the seriousness of the problem were lacking. In April 1996, and again in January 1997, NMQAAC recommended removing § 900.12(b)(4)(iv) regarding the grid related artifacts.

FDA has accepted NMQAAC's recommendation and removed this paragraph.

(Comment 316). Twelve comments requested justification, clarification, or suggested modifications for the test procedure proposed under § 900.12(b)(iv). If the issue is revisited for future regulation, the comments to this section will be reconsidered at that time.

f. *Beam limitation and light fields (§ 900.12(b)(5))*

This paragraph covers devices for limitation of the X-ray field and specifies light localizer characteristics.

Under § 900.12(b)(5)(i), FDA proposed that all systems ensure that the X-ray field can extend to or beyond the chest wall edge of the image receptor.

(Comment 317). Two comments interpreted this as a requirement that the collimator must provide separate adjustability on the chest wall edge and suggested that such adjustability is unnecessary.

FDA accepted these comments and reworded § 900.12(b)(5)(i) to clarify that the intent is not that the collimator be adjustable, but that the collimator allow complete coverage of the image receptor at the chest wall edge unless it is the intent of the operator to not do so. This requirement has been moved to the quality assurance section and appears in § 900.12(e)(5)(vii).

Section 900.12(b)(5)(ii) proposed that any system with a light field that appears to approximate the X-ray field must approximate the X-ray field to a specified tolerance and that the light must produce a minimum specified brightness. Four comments supported the alignment recommendations with the observation that, in the respondents' opinions, the alignment was more important on the chest wall edge.

(Comment 318). Two comments expressed disagreement with this requirement. In § 900.12(b)(5)(ii), FDA also proposed a definition for the mammographic source to image receptor distance (SID) that was changed slightly from the definition used for more general purpose radiographic systems in order to be more consistent with the actual usage in mammography. Two comments supported this change, two opposed it, and one respondent expressed concern that the definition of SID in this section might be confusing.

After reviewing the comments, FDA has determined that the requirements for the alignment of the light field and X-ray field and the definition of SID are adequately addressed by existing regulations in § 1020.31, and has deleted the proposed requirements from this standard. A QC test to verify alignment now appears in the quality assurance section at § 900.12(e)(5)(vii).

With respect to the proposal that the light provide a minimum illuminance, two comments supported the requirement and four comments opposed it.

FDA notes that this proposed requirement is the same as that currently required for general purpose systems covered by § 1020.31. Thus, it already applies to such collimators using such light localizers on mammography systems. FDA has chosen to restate the specification here to eliminate any confusion and to clarify that the general requirement also applies to mammography equipment. The restatement now appears under § 900.12(b)(5)(ii) in the final regulations.

Under § 900.12(b)(5)(iii), (iv), and (v), FDA proposed a phase-in of additional requirements. The first stage required all mammography systems to incorporate such a light localizer 5 years after publication. The second stage required that 10 years after publication, all mammography systems were to prevent X-ray production unless the correct combinations of field size and image receptor were selected and to prevent any exposure with an X-ray field exceeding the size of the image receptor support device.

(Comment 319). Three comments supported the requirement for the light field as proposed, with one of these urging that it be instituted at the earliest date the regulations become effective. One comment agreed that a light field, as proposed, may be a desirable feature but thought properly trained personnel are able to position the breast correctly without a light and suggested that the requirement should be deleted because, in the respondent's opinion, the cost would be too high to justify. NMQAAC supported the requirement for a light field, as proposed. Four comments supported the proposed requirements in § 900.12(b)(5)(iv) and (v) but one of these suggested that a means to override the interlocks should be provided. One comment opposed both proposals.

FDA has reevaluated these proposals and concluded that they raise safety concerns related to X-ray systems in general rather than image quality concerns. For this reason, and the cost concerns discussed previously, the agency has decided to delete both § 900.12(b)(5)(iv) and (v) from these regulations and to develop such requirements under the authority provided in the act for regulatory products subject to the Radiation Control for Health and Safety Act of 1968. Accordingly, FDA is discussing relevant changes to part 1020 with its Technical Electronic Product Radiation Safety Standards Committee.

After the revisions to the proposal were completed, there remained only two paragraphs in this provision: § 900.12(b)(5)(i), requiring beam limiting devices that allow the useful beam to extend to or beyond the chest wall edge of the image receptor; and § 900.12(b)(5)(ii), which establishes the illuminance requirement.

g. *Source-image receptor distance (SID) (proposed § 900.12(b)(6))*

FDA proposed requirements for a minimum SID for mammography systems and specified that the SID must be displayed. The agency also proposed an accuracy specification for that display. In § 900.12(b)(6)(i), FDA proposed that all mammography systems have a minimum SID of at least 55 cm.

(Comment 320). One comment recommended that FDA include a definition of ''contact mammography'' as used in § 900.12(b)(6)(i) to eliminate confusion about its meaning. Another comment supported the minimum SID as proposed, and six comments supported the concept but recommended that the minimum SID be reduced to 50 cm; NMQAAC supported the proposal as published.

In considering these comments and other more general comments relating to avoidance of unnecessary specifications that may limit future technology, FDA has decided that other requirements in the final regulations (dose, resolution/focal spot condition, and system output) make issuing this requirement unnecessary. Therefore, the limitation on the SID has been removed from the final regulations. In the future, if the agency determines that regulations covering this area are required, all relevant comments will be reconsidered at that time.

In § 900.12(b)(6)(ii), FDA proposed that each system should provide a visual indication of the SID, accurate to within 2 percent.

(Comment 321). One comment stated that the actual SID needs definition or that there should be specification of an acceptable method of verifying the SID or location of the focal spot. Other comments were concerned with uncertainties in determining the end points of the SID. One comment noted that the indication of the SID proposed in § 900.12(b)(6)(ii) might differ between systems because of differences in interpretation of the location of the image receptor. Conversely, another comment suggested that the concept of an indication of the SID, as proposed in § 900.12(b)(6)(ii), is ambiguous for those systems having multiple focal spots and anode tracks because all focal spots are not at the same location on the anode. The comment further suggested that the ''source'' be defined as the average location of all focal spots.

Another comment noted that the standards in IEC 601–1–3(point 29.203.2) specify a tolerance of 5 percent for the SID indicator and requested that FDA consider adopting that specification rather than the 2 percent proposed. One comment suggested that FDA might wish to

consider recasting the proposal of § 900.12(b)(6) as an outcomes specification. Another comment recommended that the proposed requirement in § 900.12(b)(6)(ii) for indication of SID be restated to require the indication only for variable SID units. NMQAAC recommended that the section be deleted because they believed that it would add to the equipment costs with little benefit to the quality of mammography.

FDA has accepted the NMQAAC recommendation and deleted § 900.12(b)(6)(ii). If this issue is revisited, all comments will be reconsidered at that time.

h. *Magnification (§ 900.12(b)(6) (proposed § 900.12(b)(7)))*

As proposed, this paragraph required that systems used for procedures beyond basic screening mammography have magnification capability available to the user.

(Comment 322). One comment suggested that the proposal was unclear as to the intent of ''available to the user.'' One comment incorrectly assumed that, because there was no implementation date for the requirement, all diagnostic equipment installed presently have magnification capability and will meet the requirement. One comment expressed concern that this requirement made his facility's equipment obsolete and stated that most diagnostic mammography does not require magnification.

The radiologists on NMQAAC stated that magnification is needed for noninterventional problem solving mammography. The committee debated whether to recommend to delete or change these provisions and decided not to recommend such actions.

FDA has retained the provision, but reworded parts of the proposal to clarify the intent. The changes include replacing the term ''diagnostic mammography'' with ''noninterventional problem solving mammography.'' This change was necessary because there is no general consensus as to the definition of ''diagnostic mammography.'' ''Problem solving mammography'' refers to mammography requiring techniques beyond those utilized in standard mammography of asymptomatic patients and ''noninterventional'' indicates that the procedures are noninvasive in nature. The term ''available to the user'' simply means that any attachments or accessories necessary to allow the X-ray system to perform magnification procedures must be present with the system and available to the technologist to encourage and facilitate the use of the feature.

(Comment 323). Four comments recommended that the specification be reworded to require the facility to have the capability to provide magnification instead of requiring that each system provide the feature. However, the experts on NMQAAC stressed the importance of requiring the feature in each system used for such procedures and FDA has retained the requirement.

In § 900.12(b)(7)(ii) of the proposal, FDA specified that at least one magnification setting should be in the range of 1.4 to 2.0. One comment suggested that the use of magnification greater than 1.5 is questionable and that limits for the image quality and average glandular dose should be set for these conditions.

FDA agrees, in principle, with this comment. Generally, magnification for these procedures is accepted within the range specified by the requirement and most sources seem to agree that magnification at approximately 1.5 is optimal. FDA believes that by requiring the equipment to provide magnification in the optimum range the facility will then be able to adequately perform the procedure. Some systems currently used for magnification will not meet this standard. This will not, in itself, however, force the replacement of the equipment because the unit may still be used for the general population ''screening'' of asymptomatic patients so long as it meets the other requirements.

(Comment 324). One comment noted that ''magnification setting'' as used in the proposal was not defined. Another comment stated that the method of determining the magnification, along with acceptable limits, should be specified or referenced. FDA has removed the word ''settings'' from the requirement because it might be confusing but has not added a definition of ''magnification'' to § 900.2; FDA believes that the term is generally understood to be the ratio of the source-to-image receptor distance to the source-to-object distance.

Because the proposed SID requirements were moved, proposed § 900.12(b)(7) *Magnification* has been codified as § 900.12(b)(6).

i. *System resolution (proposed § 900.12(b)(8))*

This paragraph proposed requirements for the system resolution for both contact mode and magnification mode mammography.

(Comment 325). Nine comments requested that a test procedure be specified for the contact mode requirement proposed in § 900.12(b)(8)(i). One comment suggested that a specification of the appropriate resolution target should be included along with a specification of its position in the test plane, and a requirement for an absorber in the beam to lengthen the exposure times, because very short exposures may introduce interference from gridlines.

FDA agrees with these comments and has included a description of the test conditions in the final regulations.

(Comment 326). One comment correctly noted that the requirements in proposed § 900.12(b)(8)(i) and (ii) attribute failure to meet resolution requirement to problems with the focal spot when, in fact, the cause of observed low resolution values may be some other component in the imaging chain.

FDA agrees with this comment and has rephrased the requirement.

Based on recommendations from NMQAAC, FDA has removed this requirement from the equipment standard and established a QC requirement for system resolution that is codified under § 900.12(e)(5)(iii).

In § 900.12(b)(8)(ii), FDA proposed regulating the system resolution in the magnification mode. Based on guidance received from NMQAAC, FDA has moved this requirement to the quality assurance provisions in § 900.12(e)(5)(iii), and has designated it for phase-in after 5 years. If, in that time, other values are determined to be more appropriate, the regulations will be modified accordingly.

Thus, proposed § 900.12(b)(8) *System resolution*, no longer appears among the equipment requirements.

j. *Focal spot selection (§ 900.12(b)(7) (proposed § 900.12(b)(9)))*

As proposed, this provision included several requirements for indication of the focal spot selected for use in examinations, interlocking of the focal spot with selected kVp, and alignment of the focal spot with the image receptor. FDA also proposed that the system indicate which focal spot and, where applicable, which focal spot material is selected prior to exposure. The proposal also recognized that some systems may automatically select the focal spot during the exposure and required a post exposure indication of the focal spot used during such exposures.

(Comment 327). Three comments, including that of NMQAAC, recommended that the requirements proposed in § 900.12(b)(9)(ii) and (iii), concerning indication of the target material, be linked with an ''or.''

FDA did not accept this recommendation because it would essentially eliminate the requirement for post-exposure indication of the machine selected focal spot. The agency believes that the change would modify the

requirement in a way the agency does not intend or desire because it would permit the equipment to display only the initial preselected focal spot and never indicate the actual focal spot used.

(Comment 328). Two comments supported the proposal in § 900.12(b)(9)(iv) that the system be interlocked to prevent exposure with improper or incompatible combinations of kVp and target material. One comment opposed this requirement, two requested clarification, and one requested a test procedure. NMQAAC recommended that the initial clause in the proposal be deleted.

After further consideration of this requirement, FDA concluded that the requirement was already adequately covered by requirements relating to diagnostic X-ray systems in § 1020.30(m) and has deleted proposed § 900.12(b)(9)(iv).

k. *Focal spot location (proposed § 900.12(b)(10))*

This paragraph proposed a requirement that the focal spot be located in a specific geometric relationship to the image receptor.

(Comment 329). One comment supported the requirement, five (including NMQAAC) opposed it, believing that it was unnecessary, three requested clarification on its testing, and one, recognizing its relationship to the compression paddle alignment, recommended that the provision be moved to the section on compression paddle alignment.

FDA accepted the NMQAAC recommendation and deleted this requirement from the final rule.

l. *Filtration (proposed § 900.12(b)(11))*

This proposed paragraph contained a statement requiring mammography systems to comply with the beam quality standards for half-value-layer (HVL) codified at § 1020.30(m)(1).

NMQAAC recommended that the section specifying the HVL requirements should be moved to the QC section. FDA accepted this recommendation and codified the requirements for filtration under § 900.12(e)(5)(iv).

(Comment 330). One comment suggested that the proposed rule in § 900.12(b)(11)(i) was too vague and subject to arbitrary interpretations. Another comment recommended that more precise rules be used to determine the required HVL and suggested that existing dose tables could be used to determine the desired limits. The respondent based this position on the fact that § 1020.30(m)(1) requires the interpolation or extrapolation of HVL values in the mammographic range. One comment noted that filtration is not the same as HVL; the HVL measure indicates the filtration that is in the X-ray system, but it is not an actual measurement of filtration. Two comments noted that the proposed regulations refer to § 1020.30(m)(1) for the minimum filtration requirement and incorrectly interpreted this as a lack of specification for kVp's not listed. They asked what FDA is planning to do concerning the perceived lack of regulation of filtration for kVp's below 30 kV since the table of HVL specifications does not list any values below 30 kV. One comment stated that some realistic values for expected HVL at ranges of 25 to 30 kVp should be given. One comment stated that § 900.12(b)(11)(i) seems less specific than current requirements for filtration and another comment suggested that the requirement in § 900.12(b)(11)(i) should be referenced to the most recent ACR physics manual instead of § 1020.30(m)(1).

FDA believes that the comments indicate that relationship between filtration and half-value-layer (HVL) in the mammographic energy range and the concept of mathematical extrapolation and interpolation may not be fully understood by some members of the mammography community. It is generally understood that the first HVL is an indirect measurement of the filtration in the X-ray beam. In the kVp range up to 50 kVp, the values specified in § 1020.30(m)(1) represent a beam with an inherent filtration equivalent to 0.5 mm of type 1100 aluminum. FDA notes that, although the standard relates the HVL in terms of type 1100 aluminum, it does not specify that the same alloy be used to measure the HVL. Therefore, the measurement of the first HVL and the comparison of the result to the specification indicate whether the system has sufficient filtration in the beam; if the first HVL is less than the number specified in the table, there is insufficient filtration because the HVL is a function of the filtration and the energy of the X-ray beam (kVp).

In response to the comments, FDA has provided a table of the extrapolated values of HVL in the mammography kVp range under the quality assurance provisions in § 900.12(e)(5)(iv). Values not shown may be derived by interpolation. FDA believes that providing these values, which are derived from the Federal performance standard at 21 CFR 1020.30(m)(1) and are serendipitiously identical to the ACR recommended values when the paddle is not in the beam, makes it unnecessary to reference the ACR manuals or any other external source of HVL values.

(Comment 331). Five comments supported a specification of a maximum filtration requirement in § 900.12(b)(11)(i) and another comment recommended that a maximum HVL, specified as a function of kVp, be added for each known combination of anode and filter materials. One comment noted and agreed with the deletion of the upper limits for HVL that had been proposed in previous drafts of the proposed regulations.

FDA deleted those upper limits because it had concluded that other aspects of performance and image acceptability will serve to limit the maximum filtration. Comments to the proposal have not persuaded the agency to reverse that position.

(Comment 332). One comment noted that § 900.12(b)(11)(i) references § 1020.30 and questioned the need to repeat the requirement. The comment also found the proposal ''redundant with § 900.12(b)(2),'' which requires equipment to be specifically designed for mammography. FDA does not agree that the references are redundant and has concluded that the restatement in this regulation serves to clarify and reinforce the § 1020.30 specification.

One comment suggested that the regulation be recast in terms of desired outcomes and offered this example: ''The type and quantity of filtration interposed between the source and the breast entrance surface shall be such as to provide the maximum subject and image contrast consistent with limitations on dose (§ 900.12(c) of the interim regulations) and minimum half-value layer (§ 1020.30(m)(1)).''

FDA believes this suggestion would introduce an unacceptable level of subjectivity into the evaluation process without eliminating the need to reference the specification in § 1020.30(m)(1).

FDA also reconsidered the requirements in § 900.12(b)(11)(ii) for variable filtration systems, which proposed interlocking the filtration with the target material. Upon further review, the agency concludes that requiring equipment to meet standards that ensure that the minimum filtration required in § 1020.30(m)(1) is in the beam during each exposure is sufficient to ensure proper filtration and has deleted § 900.12(b)(11)(ii) from the final regulation.

m. *Compression (§ 900.12(b)(8) (proposed § 900.12(b)(12)))*

This paragraph proposed a number of requirements concerning the application of compression. The basic proposal was

that each mammography unit should have a compression device.

(Comment 333). Five comments and several members of NMQAAC supported the proposed requirement. One comment suggested that FDA should go further and require the use of the compression device.

If the compression device is present, most technologists will use it responsibly and also recognizes that the use of an item is difficult to enforce. FDA, therefore, has rejected this suggestion.

Under § 900.12(b)(12)(i) FDA proposed that, 5 years after publication, each system would be required to be equipped with an initial, foot controlled, power driven compression and also be required to allow the user to control additional ''fine adjustment'' of the compression. The proposal required that both controls be operable from each side of the patient.

(Comment 334). Two comments stated that power-driven compression by foot control is unreasonable or unnecessary. One comment stated that FDA should delete the requirement for fine adjustment controls and the specifications on how the compression controls should operate because they will increase the cost of new equipment while providing little benefit. Another comment stated that no requirement beyond one that the system ''be capable of maintaining a force of 25 pounds for 15 seconds and have a maximum force no greater than 40 pounds when used in automatic or power driven mode'' is necessary.

In contrast, twenty-eight comments agreed that ''automatic'' power driven compression should be required of all facilities but stated that it should be put in effect immediately, not 5 years from now, as proposed. Several of these comments expressed the opinion that the technologist needs to have both hands free to optimize the breast position. Five comments stated that manual and power compression controls, as called for, are essential for quality mammography. The comments further noted that manual controls are needed for finer adjustment and that the two controls complement each other, although one comment expressed the respondent's belief that the fine adjustment should be a manual control because that type of control was reassuring to some patients. One comment recommended that the reference to ''foot controls'' be deleted since the goal of ''hands-free'' application of compression may be achievable by some mechanism other than a foot operated control.

FDA has accepted the last comment and modified the requirement accordingly. However, FDA believes that this ''hands free'' application of power compression and the fine adjustment control are basic to the delivery of quality mammography care and is retaining the requirements in the final regulations. FDA appreciates that this will have a cost impact on the installed base; however, the agency believes that the benefit to public health outweighs this cost and also notes that most of the current equipment can be brought into compliance with modifications that are far less costly than total replacement.

(Comment 335). One comment suggested that FDA might wish to recast the proposal in terms of the desired outcomes, for example:

> Means of applying compression to the breast shall be provided that; (i) allow the technologist to use both hands to position the breast while applying compression, (ii) facilitate positioning from both sides of the patient without removing hands from the patient, (and) (iii) allow a slow, final adjustment of compression.

While FDA appreciates this suggestion, the agency believes that such terms as ''allow'' and ''facilitate'' require too much subjective evaluation in the interpretation of compliance. Under some design and use conditions, certain technologists may be able to demonstrate that the equipment meets these requirements, while others may not. FDA believes that establishing reasonable standards for the equipment allows the majority of technologist the greatest opportunity to achieve optimal positioning for even the most challenging patients.

(Comment 336). One comment stated that a number of different types of mammography systems in use either do not offer automatic compression or have only automatic compression with no manual compression knob. The comment suggested it would be worthwhile to retain maximum flexibility in the final regulation to allow evaluation of this type of retrofit system, so long as the intent and specifications of the final regulations were met. A second comment stated that the ''fine adjustment compression,'' as proposed, would place a costly burden on some facilities that do not have manual compression. Another comment indicated that when requiring all units to have a power driven compression paddle activated by foot controls, as proposed, it is also necessary to have a manual compression mode as well. One comment suggested that final compression should always be done using a hand control knob, which the technologist can easily control with direct tactile feedback. One comment agreed that it is necessary to have power driven compression, as proposed, but noted that it was not necessary that the fine adjustment control be power driven. One comment noted that the proposed requirements do not preclude the equipment from having a manual compression provision.

Many of these comments resulted from misreading the proposed regulations. The proposal does not require the fine adjustment compression be a manual operation. The fine adjustment is usually a ''manual'' adjustment in that it is applied by a hand operated (''manually operated'') control. This does not imply or require the provision of a direct linked drive dependent only on the input force provided by the operator. Many of the ''manual'' knobs are actually servo-driven power compression devices that are under a more closely controlled incremental advance than that provided by the foot control and, in these cases, the ''tactile'' feed-back sensed by the technologist is not necessarily related to the force applied to the patient. As the regulations are written, the design of the equipment can provide a truly ''manual'' control for the fine adjustment, or can provide a slower power driven application that may be adjusted by a hand control or other suitable means. FDA believes that most equipment with power-driven compression already provides a fine adjustment control and that the cost impact on those facilities not presently meeting this requirement will be outweighed by the advantages to positioning and improved image quality.

(Comment 337). Five comments suggested that a requirement for maintaining compression for a specified period of time should be added and one suggested that this specification should be established for both automatic and fine adjustment compression.

FDA proposed the criteria for application of compression without stating a specified time for maintaining the compression. This means that FDA expects the compression to meet the criteria in the regulations until the compression is terminated, either by an automatic release at the end of the exposure or by operator intervention during or after the exposure. Therefore, it is not necessary to expressly establish a time limit for maintenance of compression.

NMQAAC discussed these provisions at some length and several committee members spoke about the importance of compression to the overall quality of

mammography. The committee recommended that the requirements for power driven and fine adjustment compression become effective immediately but that the requirements for the maximum force in the initial power drive remain a 5-year phase-in requirement. The agency considered the recommendation to move forward the effective date for the power driven and fine adjustment controls, but has determined that the cost considerations associated with accelerating the implementation of these requirements cannot be justified based on the expected improvements. Therefore, FDA has reworded these requirements to address some of the above comments, and has retained the effective date that was proposed.

Section 900.12(b)(12(i)(C) proposed limits on the compression force required for the automatic power compression mode.

(Comment 338). Two comments stated that the proposed requirement for 25 to 40 pounds under power driven compression was excessive and may result in patient injury.

Based on input from NMQAAC, ACR, and the general comments provided by manufacturers, FDA believes that 25 to 45 pounds is an appropriate range and presents little risk of injury to patients when applied by trained technologists.

(Comment 339). One comment observed that the proposal only limits the compression under power driven control and recommended that an upper limit be set for the maximum compression under manual control.

Although FDA had considered such an upper limit, the idea was opposed by NMQAAC because they felt that it was unnecessary. FDA is not proposing such a limit at this time.

(Comment 340). One respondent was concerned that there may be units designed to achieve the proposed compression forces but that have user adjustable controls that allow adjustment to values below the minimum proposed specification.

FDA agrees that such equipment may exist or be introduced into the market place. The agency notes that under the regulations, as codified, the requirement is for values attainable by the user. If the user has direct control over any such system adjustment, then this adjustment must be used in testing the system. If such adjustment is only available through service or installation configuration, then the unit should be tested only to the limits adjustable by the operator. Under these circumstances, the respondent's concerns are adequately addressed because any user adjustable controls must be utilized in determining the compliance of the system with the standards. FDA has moved the requirement for the range of acceptable power driven compression to the quality assurance section under § 900.12(e)(4)(iii).

Under § 900.12(b)(12(ii)(B), FDA proposed that each system have a means for manual compression release in the event of failure of other decompression mechanisms.

(Comment 341). One comment questioned if the wording meant that compression must be maintained in the event of power failure and, if so, must the required display of override status also be maintained after power failure.

FDA intends that the compression be maintained after a power interruption. However, the display of override need not continue in such circumstance because the fact that the patient is still under compression would serve as adequate indication that manual release is required.

(Comment 342). One comment noted that there were many designs currently on the market that allowed for the manual release of the compression without the presence of a specific device as called for in § 900.12(b)(12)(ii)(B). The comment requested that the proposal be reworded to emphasize the desired outcomes rather than a specific means of obtaining those outcomes.

FDA believes that the wording in the proposal does address outcomes and does not intend the provision to require any specific release design. Any mechanism that allows the manual release of compression would meet the requirement. The requirements for the compression forces and decompression have been moved, as recommended by NMQAAC, to the quality assurance section of the regulations and are addressed in § 900.12(e)(4)(iii) and (e)(5)(xi).

In § 900.12(b)(12)(iii)(A), FDA proposed that systems be equipped with different sized compression paddles matching the sizes of all full-sized image receptors provided and that compression paddles for special purposes, including those smaller than the full size of the image receptor (for 'spot compression') could be provided. FDA did not require that these special paddles be provided but included the reference to clarify that these paddles could be included in the system and are exempt from certain parts of the requirements applicable to the full size paddles.

(Comment 343). Three comments supported the requirement in § 900.12(b)(12)(iii)(A) as written. One comment recommended that the proposed requirement be expanded to require that facilities have the ''spot compression paddles'' available. NMQAAC supported the proposal as published.

FDA has done some minor rewording in this paragraph and renumbered it in the final regulations under § 900.12(b)(8)(ii)(A).

In § 900.12(b)(12)(iii)(B), FDA proposed that the compression paddle be flat and parallel to the patient support and not deflect from parallel by more than 1.0 cm at any point when under compression.

(Comment 344). Nine comments opposed the proposed requirement. Three of these suggested that this is not the best way to compress the breast because it ignores the anterior tissues and the often thicker tail of the breast. One comment stated that nonparallel paddles are useful for compression of very large breasts in the MLO view. Another comment noted that one manufacturer's equipment does not meet the proposed requirement, suggested that the subject does not need regulation, and recommended that the section be deleted. This comment maintained that the exemptions available for alternate devices would be ''much too difficult to use to allow possible improvements.'' One comment responded to FDA's request for comments on the nonparallel ''alternate design'' compression paddle by supporting the concept of allowing such a configuration under the proposed regulations. The comment further noted that some manufacturers are investigating the use of compression paddles that apply compression in nonparallel geometry and that these paddles would have difficulty complying with the regulation as proposed. One comment suggested that the proposed requirement was too restrictive, stating that several manufacturers have measured the paddle deflection on their units and found that the requirement may be difficult to meet on the 24 x 30 cm paddles. One comment suggested that the proposed specification could be improved if the tolerance were loosened, if the measured compression force were reduced, or if the allowable flex were expressed as a function of the applied force.

Two comments asserted that the proposed regulation in § 900.12(b)(12)(iii)(B) places too great an emphasis on the position of the compression paddle, but does not address the position of the film in the patient support. These comments recommended that the regulations

address the film location with respect to the edge of the patient support and relax the requirements for the compression plate. Three comments suggested that the description of the test method as proposed in § 900.12(b)(12(iii)(B) should be deleted and that testing procedures should be left to the medical physicist to determine, or be included in a companion manual prepared by FDA. Fifteen comments neither supported nor objected to the proposed requirement, but were concerned with the test procedure as proposed and suggested modifications or requested clarification of the procedure.

NMQAAC discussed this section at some length. Some members and consultants were concerned that the specifications in the proposal would limit the introduction of new equipment and, even though the regulations provide procedures for obtaining approval for alternate standards, wanted to modify the requirement. Experts on the committee stressed that the purpose of this regulation was to eliminate those worn and faulty compression devices that were intended to be flat and parallel by design but which, through use, now flex unacceptably. After consideration, the committee recommended that the requirement remain but that a new provision be added that addressed those paddles that by design were not intended to remain straight and parallel under compression. They also recommended that the test procedure described in this section be deleted as a requirement because it could be determined by the physicist during the survey.

In response to the public comments and NMQAAC recommendations, FDA has made changes as outlined below. FDA is deleting the provision that established a test procedure for this section. The requirements have been modified and renumbered as § 900.12(b)(8)(ii)(B) and a new § 900.12(b)(8)(ii)(C) requires that all paddles intended by the manufacturer's design not to be flat and parallel under compression must meet the manufacturer's design specification and maintenance requirements. The agency will revisit and modify its proposal for the test procedure for this section in the future and all comments regarding the procedure will be considered again in that process.

Under § 900.12(b)(12)(iii)(C) and (D), FDA proposed that the chest wall edge of the compression paddle should be straight and parallel to the edge of the image receptor and that the chest wall edge of the compression paddle should not interfere with the chest wall edge of the image.

(Comment 345). Two comments requested clarification on how straight and how parallel the requirement intended the chest wall edge of the paddle to be. One comment agreed with the intent of the proposed regulation, but expressed concern that varying interpretations of the written regulation will lead to confusion in enforcement. This comment recommended that, if such specifications are included in the final regulations, there should be some tolerance specified that is both affordable and effective in the improvement of mammography.

FDA notes that the intent of this section is to eliminate the older style compression paddle that had a curved chest wall edge. The agency believes that the words straight and parallel are well understood but will address concerns raised by the comments through issuance of a guidance on this paragraph that contains a test procedure facilities may utilize. The description of this procedure should also clarify any confusion regarding FDA's interpretation of the regulation.

In § 900.12(b)(12)(iii)(D), FDA had proposed that the chest wall edge of the compression paddle should be bent upward.

(Comment 346). One comment recommended that the proposed regulation include a requirement that the chest wall edge of the paddle be perpendicular to the surface of the compression plate. Another comment stated that the use of ''should'' in § 900.12(b)(12(iii)(D) has little meaning and is unenforceable.

NMQAAC discussed both paragraphs and did not recommend any changes. FDA notes that this provision was not intended to establish a mandatory requirement but to clarify that such a design, intended to enhance patient comfort, was permissible. This requirement has been codified under § 900.12(b)(8)(ii)(E) in the final regulations. The word ''should'' has been replaced with ''may'' in the final rule. FDA does not agree that it is advisable to require the chest wall edge to be perpendicular to the surface of the compression paddle since this could lead to sharp edges that might cause patient discomfort.

Under § 900.12(b)(12)(iv)(A), FDA proposed that, 5 years after the publication date of the final regulations, the edge of the compression paddle shall align with the chest wall edge of the image receptor to within 1 percent. Proposed § 900.12(b)(12)(iv)(B) further restricted the alignment to within 2 millimeters 10 years after publication and § 900.12(b)(12)(iv)(C) proposed a test procedure for the requirement.

NMQAAC recommended that the § 900.12(e)(12)(iv)(A) be moved to the QC section of the final regulations and that the requirements should go into effect at the earliest opportunity. NMQAAC also recommended that the requirement under § 900.12(b)(12)(iv)(B) and (C) be deleted because the committee believed the proposed 2-millimeter requirement was too stringent. The proposed 2-millimeter requirement and the test procedure have been deleted and the final regulation regarding compression paddle-image receptor alignment was moved to the quality assurance section and is codified under § 900.12(e)(5)(vii)(C) where it will become effective at the earliest effective date.

(Comment 347). One comment recommended caution in specifying these alignment requirements because they might limit design in some areas of new technology. The comment recognized that these proposed specifications are only applicable to film-screen systems, but expressed concern that the concepts might carry over into new technology areas.

FDA assumes that this comment was directed toward the issue of image receptor size for digital systems, but does not anticipate any conflict.

(Comment 348). Eleven comments agreed with tightening the tolerance for alignment as proposed in § 900.12(b)(12)(iv) but suggested that only a positive misalignment should be allowed.

FDA agrees and accepts these comments.

(Comment 349). Eight comments noted a typographical error in § 900.12(b)(12)(iv)(A). FDA has corrected this.

(Comment 350). Three comments recommended that the ''October 1, 2000'' effective date be deleted and that the requirement go into effect in the earliest phase because, in the respondents' opinions, the vast majority of systems already meet this requirement.

FDA agrees with these comments and has accepted this recommendation to move the effective date forward.

(Comment 351). Six comments expressed concern regarding the test for this paragraph.

These comments will be reconsidered when FDA publishes its guidelines for the QC test.

Under § 900.12(b)(12)(iv)(D), FDA proposed that the alignment criteria for the contact mode should also be applicable to the magnification mode 10 years after the publication of the final regulations and proposed a test procedure.

(Comment 352). Five comments suggested that the requirement was unnecessarily restrictive and should be dropped. Four comments supported the proposed requirement, believing it serves to ensure the accuracy of the alignment of the edge of the compression paddle with the edge of the image receptor. One comment recommended a rewording for the requirement. Two respondents expressed concern regarding the test procedure. NMQAAC suggested that the requirement in the magnification mode was unnecessary and should be deleted.

After reviewing the comments, FDA has accepted the NMQAAC recommendation and deleted the requirement for paddle alignment in the magnification mode.

Under § 900.12(b)(12)(v), FDA proposed that, 5 years after publication of the final regulations, all systems should display the compressed breast thickness. The proposal also established a test procedure for the requirement.

(Comment 353). One comment pointed out that current indicators of compressed breast thickness are grossly inaccurate for a number of reasons, including paddle and compression arm flex, lack of uniformity across the breast, and differences in the location at which various manufacturers determine the breast thickness (since there is no agreement where the breast thickness is to be measured). Two comments recommended that the word ''correct'' be inserted between ''the'' and ''compressed'' in § 900.12(b)(12)(v). One manufacturer requested an exception for its product because the measured breast thickness read out could be off by 0.6 to 1.0 cm for their paddle. One comment expressed concern that there was no clear specification to the accuracy of the indicated value proposed in § 900.12(b)(12)(v)(A). NMQAAC discussed this provision at its April 1996 meeting and recommended that the requirement for a display remain but that no accuracy specification be associated with the display. NMQAAC revisited the issue at its January 1997 meeting but did not change its recommendation. Another comment suggested that the proposed requirement should apply only to equipment that uses the compressed breast thickness in an algorithm to determine technique factors. One comment supported the proposed requirement in § 900.12(b)(12)(v)(A) because it is especially important for implant patients, but recommended that it go into effect 5 years after the effective date of the regulations rather than 10 years after, as proposed.

FDA has reviewed the comments and reassessed the need for this requirement. The practical application of the information provided by the display to the mammography process appears to be questionable and the concept of having a display that has no associated accuracy is of debatable value. FDA has decided to remove § 900.12(b)(12)(v) from the final regulations in accordance with the agency's desire to minimize costs, as discussed previously. All comments requesting clarification or suggesting modification to the test procedure will be considered again if FDA revisits this requirement.

The portions of proposed § 900.12(b)(12) that have been retained in the equipment provisions were codified under § 900.12(b)(8).

n. *Technique factor selection and display (§ 900.12(b)(9) (proposed § 900.12(b)(13)))*

In this paragraph, FDA proposed requirements for the selection and display of technique factors.

FDA proposed in § 900.12(b)(13)(i) that every system shall have the capability for manual selection of mA's or, at least, of mA or time. No public comments addressed this issue. NMQAAC discussed the proposal at both the April 1996 and the January 1997 meeting and supported the proposal. FDA reworded the requirement slightly before codification to clarify its intent. Because of the deletion of paragraphs listed earlier in the proposal, paragraph § 900.12(b)(13) has been codified as § 900.12(b)(9), and this paragraph became § 900.12(b)(9)(i) in the final rule.

Under § 900.12(b)(13)(ii), FDA proposed that all technique factors be clearly displayed at the control panel prior to exposure. At § 900.12(b)(13)(iii), the agency proposed that such factors be preindicated in the AEC mode.

(Comment 354). One comment recommended FDA clarify that the specification in § 900.12(b)(13)(ii) applies only to the manual mode of operation. A comment on § 900.12(b)(13)(iii) requested clarification of which technique factors were intended to be covered by this requirement. At its April 1996 meeting, NMQAAC also expressed some confusion regarding the same issue. Another comment recommended that the requirements of § 900.12(b)(13)(iii) and (iv) be combined.

FDA believes that requirements for preindication and postindication of the technique factors should be presented under separate paragraphs and has not accepted this last comment. FDA did clarify § 900.12(b)(13)(ii) and (iii) and combined them into a single provision at § 900.12(b)(9)(ii).

Under § 900.12(b)(13)(iv), FDA proposed that, after AEC exposure, the system should indicate the actual kV and mA's used during the exposure.

(Comment 355). Two comments recommended that this requirement be deleted or its implementation date be delayed because the replacement or retrofit of many older units might be costly. Another comment stated that a mA's readout, as proposed in § 900.12(b)(13)(iv), has not been proven necessary. NMQAAC discussed this issue and the cost concerns related to retrofits to provide the postexposure mA's indication. The committee supported the requirement but requested some wording changes to clarify the meaning of mA's indication.

FDA has retained this provision because it concluded that the costs associated with the possible retrofits are not significant enough to outweigh the benefits and has included it in the final regulations under § 900.12(b)(9)(iii).

Under § 900.12(b)(13)(v), FDA had proposed that each unit provide an indication of kVp that was accurate to within + 5.0 percent of the actual kVp.

(Comment 356). Five comments agreed with the proposed five percent accuracy specification, but another comment suggested that the requirement for kVp accuracy of + 5.0 percent was not justified because there was no definition of what kVp really means and no calibration available for kVp meters. Another comment stated that ''5 percent of the actual kVp as proposed in (b)(13)(v), is a very large discrepancy,'' noting that 5 percent of 30 kVp allows 31.5 kVp, which, in the respondent's opinion, presently is considered to be unacceptable. The comment further suggested that § 900.12(b)(13)(v) be changed to read: ''All indications of kVp shall be within 1 kV of the actual kVp.''

In § 1020.30 FDA defines kVp to mean the maximum value of the potential difference across the X-ray tube during an exposure. FDA agrees with the comment that the + 5.0 percent accuracy is a large discrepancy and notes that it is the same specification currently established by the most recent revision of the ACR manuals. The agency intends to provide additional information regarding compliance with this requirement.

(Comment 357). Three comments, including one from NMQAAC, noted that there was a conflict between the kVp accuracy specification at § 900.12(b)(13)(v) and at § 900.12(e)(5)(ii)(A). NMQAAC also recommended that the requirement be moved to the quality assurance section

and that the + 5.0 percent accuracy specification be retained. FDA has accepted these recommendation and the requirement now appears in the final regulations under § 900.12(e)(5)(ii) and includes the + 5 percent accuracy specification.

In § 900.12(b)(13)(vi), FDA proposed that, 10 years after the publication of the final regulations, each X-ray unit used for mammography would be required to have a specific range of kVp and mA's selection and that adjacent selections of the kV selection and adjacent selections of the mA's should not vary by more than a prescribed amount. The public comments regarding this section were overwhelmingly against including these proposals in the final regulations. NMQAAC supported the proposals but only marginally so, with many opposing opinions. FDA has reconsidered the advisability of including these specifications in the final regulations, based in part on the public comments and in part on the difficulty in predicting the necessity for these limitations 10 years in the future and has deleted all requirements proposed under § 900.12(b)(13)(vi) from the final regulations.

o. *Radiation output (proposed § 900.12(b)(14))*

This paragraph proposed setting a minimum value for radiation output per second of mammography X-ray equipment, with an increase in that minimum value to occur 5 years after publication. This section has been codified in the quality assurance section of the final regulations.

(Comment 358). Two comments agreed with the requirement proposed in § 900.12(b)(14)(i), with one urging that the requirement be fully implemented at the earliest possible date rather than being phased-in. One comment suggested that the proposed requirements in § 900.12(b)(14)(i) and (ii) might actually be in conflict with each other. FDA reviewed these provisions and does not see a conflict because clause (i) specified an exposure rate and (ii) specified a time over which that rate must be met. However, in response to other concerns, as outlined in the preamble to the quality assurance section, FDA has modified the requirement to clarify that the specification is to be an average over three seconds and not an instantaneous rate measurement.

(Comment 359). One comment suggested that the proposed requirement in paragraph (b)(14)(i) be replaced by the equivalent air kerma expressed in milligray (mGy). The guidelines followed by FDA in the writing of regulations specify that all numerical limits, where applicable, be expressed in terms of the International System (SI) of Units, the internationally accepted standard, followed by the more common equivalent in parentheses.

In the proposed regulations, FDA had represented radiation limits in terms of exposure expressed in the SI unit of coulomb per kilogram (C/kg). Although C/kg is the correct SI unit for exposure, it is an awkward unit for the actual operating ranges of exposure (10–4 C/kg) of mammography systems. FDA believes now that it would be more advantageous to specify radiation limits in terms of the alternate quantity air kerma expressed in the SI base unit of gray (Gy). Air kerma, which is defined at § 900.2(d), is the sum (per unit mass of air) of the initial kinetic energies of all the charged ionizing particles liberated by the X-rays. At the X-ray energies typically used in diagnostic radiology and mammography, values for air kerma are practically indistinguishable from values of absorbed dose in air. Air kerma is increasingly accepted in the international community as the quantity preferred in the specification of radiation delivered, and it is being proposed to replace exposure in amendments in 21 CFR part 1020. Because amendments to those standards are not final, the units were not used in the proposal. However, FDA is replacing the quantity exposure with the quantity air kerma in these final MQSA regulations because it anticipates that parallel changes will be made in the international standards and part 1020.

(Comment 360). One comment suggested that FDA recast proposed § 900.12(b)(14)(i) as a performance objective, such as: ''The radiation output, in terms of exposure rate, at clinically useful kVp's shall be sufficiently high to avoid exposure times of such duration that loss of resolution due to motion or excessive dose due to film reciprocity failure is expected to occur.''

FDA appreciates the benefits of adopting performance standards when appropriate but believes that in this case the suggested wording introduces an unacceptable level of subjectivity into determining compliance.

(Comment 361). One comment recommended that the test procedure proposed to measure radiation output in § 900.12(b)(14)(iii) specify the position of the compression paddle during the measurement.

FDA assumes this comment is expressing concern regarding the scatter contribution to the reading and its variability depending on the distance the paddle is located from the detector. FDA recognizes the possible effects of scatter on this measurement but does not believe the contribution is of sufficient concern to warrant the prescription of paddle position relative to the detector. In clinical use, the paddle is obviously in contact with the breast. If a facility wishes to test with the paddle in a similar position, FDA has no objection. Similarly, if the paddle is moved nearer to the focal spot, FDA would find this acceptable. FDA does, however, require the compression paddle to be in the X-ray beam between the source and the detector as was specified in § 900.12(b)(14)(iii).

(Comment 362). One comment suggested that FDA require that compliance with § 900.12(b)(14) be determined ''with the phantom in the beam and that the exposure be completed within 2.5 seconds.''

FDA believes that placing any phantom in the beam during this test would not improve this test and that the three second exposure proposed is both reasonable and appropriate for this requirement.

(Comment 363). Two comments suggested that compliance with § 900.12(b)(14)(i) should be determined at a routine clinical kVp instead of the proposed 28 kVp. FDA notes that 28 kVp is used clinically for mammography, although not as frequently as other kVp values. It was selected first by the American Association of Physicists in Medicine and then by the ACR/CDC Imaging System Focus Group as the standard kVp to be used in association with their radiation output specifications. These specifications were utilized by FDA in establishing this radiation output requirement. If a different kVp were selected, the radiation output would likely have to be modified; however, professional consensus on what modifications would be appropriate is presently lacking. The agency, therefore, does not accept these comments.

(Comment 364). One comment recommended that the proposed requirements under § 900.12(b)(14) should be made part of § 1020.31 so that uniform requirements would be ensured nationwide. FDA reiterates its previous position that this would not achieve the desired impact on the installed base of mammography equipment. FDA believes that most modern mammography systems can meet this requirement. However, the agency is considering parallel requirements under § 1020.31 to ensure that future production is compliant.

(Comment 365). One comment supported the test procedure specified in § 900.12(b)(14)(iii) as being an

improvement over the current specification. Another comment suggested that the requirement in § 900.12(b)(14)(i), as written, should only apply to a molybdenum/molybdenum Mo/Mo anode/filter combination because other target-filter combinations may not need to meet the requirement to deliver adequate imaging.

NMQAAC supported the proposed requirements, but suggested that the specifications should be limited to Mo/Mo target-filter units only. They also recommended that all of § 900.12(b)(14) be moved to the quality assurance section.

FDA has accepted NMQAAC recommendations to limit the requirements to Mo/Mo target-filter units and to codify the requirement with the QC requirements.

(Comment 366). One comment noted that xeromammography equipment might not meet these proposed requirements.

FDA believes that xeromammography units should be able to meet the requirement, as proposed, but with the acceptance of the Mo/Mo limitation discussed above, the requirement would no longer be applicable to xerox systems, which incorporate tungsten targets.

(Comment 367). One comment suggested that the proposed requirements of § 900.12(b)(14)(i) and (iii) need to be linked in order to explain where the output is to be measured.

FDA does not agree with this comment although it has reworded the proposed § 900.12(b)(14) for clarification. The provision has been codified as § 900.12(e)(5)(x).

p. *Automatic exposure control (§ 900.12(b)(10) (proposed § 900.12(b)(15)))*

As proposed, this paragraph required that each mammography system have an automatic exposure control (AEC) for mA's, established a specification for the AEC reproducibility, and set requirements for the indication of the AEC detector positions and selected location.

(Comment 368). One comment suggested that the requirements proposed in § 900.12(b)(15) should be prefaced with a statement that they are intended to apply only to film-screen modalities. A related comment reported that xeromammography systems do not have AEC controls as required in § 900.12(b)(15) and that this would bar their use.

FDA agrees with these comments and has rewritten this requirement to limit it to screen-film mammography systems.

Under § 900.12(b)(15)(i), the proposal required all AEC devices to be operable in each equipment configuration provided and gave examples of common configurations.

(Comment 369). Several comments sought to limit the applicability of this requirement in different ways. One comment supported the proposed requirements in § 900.12(b)(15)(iv)(A) and (B) as a means to ensure appropriate detector location and thereby avoid repeat exposures and reduce patient dose. One respondent did not believe that the automatic exposure control photo-timing proposed in § 900.12(b)(15)(i) is significant in obtaining satisfactory diagnostic mammograms. Three comments recommended modifying § 900.12(b)(15)(i) by replacing ''of equipment configuration provided'' with ''where applicable.'' The comments further suggested that the examples of equipment configurations in § 900.12(b)(15)(i) be deleted. One comment agreed with the April 1996 NMQAAC recommendation that the requirements proposed in § 900.12(b)(15)(i) should be limited to clinically used configurations.

FDA remains convinced that the use of AEC devices on mammography equipment is an aid to quality mammography and believes that requiring it for ''all combinations of equipment configuration provided'' is appropriate and necessary. The agency notes that the requirement applies to the configuration of the individual unit. For example, if the unit is not provided with magnification capability, then it would not be required to have a functioning AEC in a nonexistent magnification mode. The agency also notes that NMQAAC reversed its April 1996 position during its January 1997 meeting and concurred with the requirement as proposed.

Under § 900.12(b)(15)(ii), FDA proposed that the AEC be capable of providing automatic mA's selection.

(Comment 370). One comment recommended deleting this requirement, stating ''that it is the purpose of AEC to provide automatic mA's selection'' and, therefore, the requirement was redundant. One comment requested clarification of the phrase ''automatic mA's selection.'' Another comment asked whether § 900.12(b)(15)(ii) required automatic termination of exposure or automatic display of mA's and questioned why the AEC should be able to automatically select mA's.

FDA defines an automatic exposure control as a device that automatically controls one or more technique factors in order to obtain a desired quantity of radiation at a preselected location. Such a device would automatically terminate the exposure when the selected quantity of radiation had been delivered. This definition does not restrict the technique factor(s) that may be selected; the control of target material, focal spot, filtration, time, mA, and/or kVp are all viable options for such a device. Because the mA's is the product of time (in seconds) and mA, the control of time and/or mA represents control of the mA's; therefore, AEC's generally function by controlling mA's and/or kVp. FDA was initially concerned that an AEC that controlled kVp alone, without capability to control mA's, could not adequately ensure the small incremental changes in radiation that are often necessary in mammography. FDA has reconsidered this position because it has concluded that any such device that reaches the marketplace would provide the necessary ranges of adjustment in order to have been approved under the FDCA's requirements for safety and efficacy of new devices. Therefore, FDA is removing the requirement proposed in § 900.12(b)(15)(ii) that all AEC devices provide automatic mA's selection.

Under § 900.12(b)(15)(iii), FDA proposed a limit on the reproducibility of the AEC.

(Comment 371). One comment suggested the wording be changed to include ''for each target/filter combination.''

FDA believes the change is not needed; because no target-filter combinations were specified in the regulation, all combinations are subject to the requirement.

NMQAAC recommended that this requirement be moved to the quality assurance section. FDA has accepted this recommendation and the specification for the evaluation of the AEC reproducibility is codified in § 900.12(e)(5)(i).

Under § 900.12(b)(15)(iv), FDA proposed requirements regarding the positioning flexibility of the AEC detector, visual location of the available detector positions, and indication of which AEC detector location was selected.

(Comment 372). Two comments recommended that the proposal be expanded to require increased flexibility in placement of the AEC detector. One comment commended the proposed requirement for AEC positions to be indicated at the input surface of the breast compression paddle. The comment believed that this requirement would improve the quality of imaging and prevent repeat images. Two

comments suggested that FDA add a requirement specifying the necessary accuracy of the indication of both the size and available position of the AEC detectors. The respondents' suggested the indication might depend on magnification of the indication resulting from various breast thicknesses.

FDA interprets these comments to mean that a projected indication on the input surface of the breast might vary in size and location depending on the magnification induced by the displacement of the input surface caused by various breast thicknesses. FDA agrees that this might occur and notes that such a system would be a design that might not be able to meet the requirements.

FDA intends the indications of the size and location represented on the compression paddle to be representative of the actual size and location of the detectors as they would appear if marked on the breast support device. The agency anticipates no confusion will be caused by varying displacement of the paddle from the patient support since the indication of size and position will remain constant.

(Comment 373). One comment suggested that the indicators should not ''give rise to artifacts in the image.''

FDA believes that any such artifacts will be detected and corrected during the normal QC process and, therefore, modification of this requirement is unnecessary.

(Comment 374). One comment stated that this requirement leaves too much room for interpretation and would be very difficult to inspect against. The comment suggested one could argue that merely knowing the position via the handle that moves the detector would be adequate for proper detector positioning. The comment further stated that all current units do provide clear indication of detector position, which is visible from both sides of the patient, and that the requirement should be removed.

FDA does not agree that the requirement is subject to conflicting interpretation or would be difficult to inspect, but does agree that the location of the position selector would be an adequate indication of which detector position had been selected (although it would not indicate the detector position itself). FDA also does not agree that the installed base of systems all provide such flexibility or indications and remains persuaded that the requirement will provide useful tools for the technologist.

NMQAAC recommended that FDA delete the proposal that the selected detector position be visible from both sides of the patient because they did not consider it of sufficient importance to require in the regulations. FDA has adopted this recommendation and the requirement has been amended accordingly.

Under § 900.12(b)(15)(v), FDA proposed that the operator be able to vary the optical density from the normal density setting. No specific comments were received on this proposal and FDA codified this requirement without change.

Under § 900.12(b)(15)(vi), FDA proposed that, 10 years after the publication of the final regulations, each unit would be required to provide four steps above and four steps below the normal optical density setting and proposed limits for the acceptable variability between adjacent settings on this control.

(Comment 375). FDA received a large number of comments on this section. The overwhelming majority were opposed to the requirement because of concerns regarding the wording of the provision, the perceived cost to facilities, the range of control to be provided, the incremental difference between adjacent settings, and the necessity for the requirement. In response to these comments and because of agency concerns regarding costs, FDA concluded that the proposal should be deleted from the final regulations and that further study should be undertaken to determine if future requirements in this area are warranted. If regulations or guidelines are proposed later, the individual comments will be reconsidered at that time.

Under § 900.12(b)(15)(vii), FDA proposed requirements for the optical density variation permitted with a screen-film mammography system under AEC.

(Comment 376). Three comments supported the proposed requirement in paragraph (b)(15)(vii) because it evaluates the equipment performance when used on breasts of various size and density. Two comments indicated that § 900.12(b)(15)(vii) was not stringent enough and one of these recommended that an initial value of 0.15 OD should be specified.

FDA disagrees with this comment because it believes that the initial value should remain the same as that used in the interim regulations. NMQAAC recommended that these requirements be moved to the quality assurance section and FDA agreed. The requirements have been codified under § 900.12(e)(5)(i).

In the proposal, FDA had specified that the system meet the requirements for AEC reproducibility at each available detector position.

(Comment 377). Three comments suggested that the test under § 900.12(b)(15)(vii) is necessary for only one detector position because the detector and associated electronics do not change.

FDA disagrees with these comments because some AEC detectors utilize individual detectors that are permanently fixed in position. The switching of position is actually a change in contact points or system logic to read the selected position. In such cases, the testing of one position provides no indication of the function at other locations.

(Comment 378). One comment suggested that the testing of photo-timer tracking with dosimeter positioning is usually not necessary unless multiple detectors are used.

The agency believes that when the process is accomplished by the relocation of the same detector to different positions, the functioning of the detector at each detector location is not guaranteed by testing at only one position. This could be influenced by broken wires, poor connections, or dirty contacts in the system.

(Comment 379). One comment stated that testing of the AEC at all detector positions will be dependent on the dimensions of the phantom. The respondent stated that the commonly used 10 cm x 10 cm phantom may not be large enough for all positions and that this will drastically increase the time required to perform this test.

FDA does not agree with this comment. The phantom could be placed near the focal spot and thereby cover all available detector positions without being repositioned.

(Comment 380). One comment suggested that with multiple detectors it is not necessary to test the tracking over the entire range of phantom thicknesses.

FDA interprets this comment to mean that, once the detector reproducibility at each position has been established, the testing of reproducibility for additional thickness need be performed at only one position. FDA does not agree with this comment; it does agree, however, that when one detector is used and moved from position to position, once it is established that the detector is reproducible over the entire range of thicknesses at one position, it is only necessary to establish the correct functioning for one thickness at each other position. In response to these comments and in recognition of the costs associated with testing reproducibility at multiple positions, FDA has deleted the specification for

testing at each detector position. Because the agency remains convinced that the best way to ensure that the detector(s) functions properly at each position is to test it/them at each position. FDA encourages facilities and the medical physicists to include such testing as a routine part of the annual survey. The remaining provisions of proposed § 900.12(b)(15) are codified as § 900.12(b)(10).

q. *Disabled examinees (proposed § 900.12(b)(16))*

In this paragraph, FDA proposed that each facility choosing to schedule disabled patients have equipment and protocols in place to ensure that the facility could adequately accommodate such disabled patients. This proposal did not require each facility to accept disabled patients, but did require those doing so to be capable of performing the service.

(Comment 381–382). Many comments expressed the mistaken belief that FDA was seeking enforcement powers under the American with Disabilities Act (ADA) or to duplicate the ADA.

Other comments on this section ranged from calling the requirement too lenient to calling it unnecessarily intrusive. The majority of the comments, although not opposed to accommodating disabled patients, were concerned that the screening of patients prior to their examination would be difficult or impossible because many appointments are not made by the patient. Comments also expressed concern that accepting disabled patients under this requirement would obligate facilities to be able to accommodate all disabled patients. Some comments also questioned whether there was equipment available that could offer this range of use.

Another area of concern was related to mobile units and facilities which, because of their size and stand-alone nature, would be difficult to adapt to accommodate the range of disabilities the facilities might encounter. NMQAAC consumer representatives supported this section and urged FDA to require facilities to either serve disabled patients or refer them to a facility that can. Other comments questioned the value of referrals, citing lack of knowledge regarding other facilities' equipment, staff, and ability to deliver the services necessary.

Because of the lack of consensus on the need for this requirement and the concerns raised in the comments, FDA has decided to delete the proposed requirement and revisit it at a future date if a problem is perceived. FDA strongly urges facilities to voluntarily institute procedures that will direct patients with disabilities to facilities that are capable of serving this population. The agency believes that local consumer groups and all accreditation bodies can pool information and educate the public and the mammography community about the availability and locations of such services.

r. *X-ray film (§ 900.12(b)(11) (proposed § 900.12(b)(17)))*

In this paragraph, FDA proposed a requirement that X-ray film used for mammography must be designated for such use by the film manufacturer.

(Comment 383). One comment supported the proposed requirement. Three comments suggested that it was too vague, one comment questioned how one would know if a manufacturer's designated mammography film is adequate for doing quality mammography under the requirements, and another suggested the adoption of the storage recommendations from ACR's *Recommended Specifications for New Mammography Equipment*. NMQAAC supported this requirement as proposed.

FDA has not proposed regulations governing film storage because it believes that each facility should follow the manufacturer's instructions for the particular film being used. The goal of this requirement is to ensure that the film used by the facility is considered, at least by the manufacturer, as being suitable for mammographic use. The regulation is not intended to establish standards for film; the only requirement placed on the facility is to check that the film it uses has been designated by the manufacturer for mammography. The requirement is not vague once its limited scope is understood. FDA codified this requirement, without change, in § 900.12(b)(11).

s. *Intensifying screens (§ 900.12(b)(12) (proposed § 900.12(b)(18)))*

FDA proposed in this paragraph that only intensifying screens that have been specified by the manufacturer as appropriate for mammography may be used for mammography.

(Comment 384). One comment supported the proposed requirement. Again, one comment questioned how a facility would know if a manufacturer's designated mammography screens are adequate for doing quality mammography under the proposal. Another comment stated that xeromammography systems do not use intensifying screens and that § 900.12(b)(18) would serve to ban their use.

FDA does not intend a specification about screen requirements to apply to any modality that does not use screens in the production of its images. Therefore, the agency sees no impact of this requirement on xeromammography. Although NMQAAC supported the requirement, one member expressed concern that the wording of the proposal implied that the facility was responsible for matching the spectral sensitivity of the film and the screen. As explained in connection with the mammography film specification above, the intent of the requirement is not to address the quality of the product, but rather to ensure that it is one intended by the manufacturer to apply to mammography. In general, the facility is responsible for matching the spectral sensitivities of the screen with the film. However, the facility is expected to use the information provided by the manufacturers and not to derive the information independently. FDA has reworded the requirement to clarify this point and codified it as § 900.12(b)(12).

t. *Film processing solutions (§ 900.12(b)(13) (proposed § 900.12(b)(19)))*

In this paragraph, FDA proposed that facilities use film processing solutions capable of developing films in a manner equivalent to the film manufacturer's minimum specifications.

(Comment 385). Three comments supported this proposed requirement and requested that guidance documents be established for this area. Six comments suggested that the word ''minimum'' be deleted because, in the respondents' opinions, most facilities generally comply with the regulatory requirement and the regulation should encourage them to meet more than the minimum. FDA appreciates these comments and notes that facilities are free to exceed this minimum; the requirement, however, is intended only to establish that facilities comply with the manufacturers' minimum standards.

(Comment 386). Three comments questioned how a facility could demonstrate equivalence under § 900.12(b)(19) because some manufacturers of film processing chemicals refuse to acknowledge that other vendors' chemicals produce ''equivalent'' results. The comments requested that the wording be changed to clarify compliance.

FDA believes these comments are similar to the ones regarding quality of the film and screens used in mammography. It is not the intent of the requirement that the facility experimentally determine the compatibility of various solutions with the film, but only that the facility obtain documentation from the suppliers showing that their products are intended to be used for processing the

particular film used by the facility and that they provide results consistent with the film manufacturer's specifications. The facility would only be required to establish the equivalence independently if no documentation, in the form of labeling or specifications, were available from the chemical or film supplier.

(Comment 387). One comment questioned how the requirement can be met when the film manufacturer does not manufacture chemicals for film processing.

FDA notes that, in such cases, it would likely be easier to establish equivalence because the film manufacturer would specify the requirements for the processing as opposed to a manufacturer that supplies both film and chemicals and is likely to specify solutions only by name rather than characteristics.

(Comment 388). One comment recommended that FDA allow accreditation bodies to review and monitor the use of chemicals for film processing and eliminate the requirement from the regulations.

Although the agency is continually working with the accreditation bodies to divide responsibilities when such division is useful and possible, FDA did not adopt the recommendation. The MQSA requirements, even when administered by the accreditation bodies, are implemented through Federal standards. FDA may consider requiring accreditation bodies to collect and monitor information about chemicals used for film processing in the future. NMQAAC agreed with the requirement as proposed. FDA has codified the requirement in the final regulations under § 900.12(b)(13).

u. *Lighting (§ 900.12(b)(14) (proposed § 900.12(b)(20)))*

In this paragraph, FDA proposed a requirement that facilities provide special lights for use during interpretation with variable luminance capable of producing light levels greater than that provided by the viewbox.

(Comment 389). Four comments supported the proposal. One stated that ''it might reduce the number of retakes, and provide better detail to the interpreting physician.'' Two comments noted that the light should be required wherever the interpreting physician is reading films, but that it may not be necessary at all locations where images are taken. One comment noted that the proposed requirement in § 900.12(b)(20) was for a ''bright light'' or ''hot lamp'' for viewing dense areas of films. The comment suggested that the purpose of the lamp should be included and that it should only be required for facilities that use the screen-film modality.

FDA agrees that the light is only required where mammograms are interpreted but recommends that it may be useful to the technologist in evaluating the quality of the films. FDA also agrees that facilities not interpreting screen-film mammograms, or not reviewing previous screen-film mammograms for reference, do not need these special lights.

(Comment 390). Two comments stated that a fixed output lamp may give the same information as the variable output ''hot lamp'' proposed. NMQAAC supported the requirement, but recommended that the word ''variable'' be removed because it is the increased intensity and masking provided by the light rather than any variability in output that actually enhance the reading of the image.

FDA has accepted these suggestion and has reworded the final requirement accordingly.

(Comment 391). One comment expressed difficulty imagining the benefits of this requirement to the patient.

FDA believes the usefulness of this device is well established, especially in view of the trend toward denser films in mammography; by optimizing interpreting conditions for physicians, the regulation increases the likelihood that the patient's mammogram will be accurately interpreted.

(Comment 392). One comment recommended that FDA allow accreditation bodies to review and govern the proposed requirement in § 900.12(b)(20), and eliminate it from the regulations. As indicated above in response to a similar comment by the same individual.

FDA has not adopted the recommendation, although it may consider requiring such action by the accreditation bodies in the future.

(Comment 393). Four comments suggested that the proposed requirement was too vague. One comment suggested that the requirement be reworded to specify that a ''spot lighting'' device be provided.

FDA agrees with these comments and amended the final requirement to clarify this point.

(Comment 394). A number of comments chose this section to offer suggestions regarding requirements for the viewbox or the viewing conditions. FDA has discussed those comments in the general equipment section above.

Because of the deletion or movement of other paragraphs in the equipment portion of the proposed regulations, the reworded § 900.12(b)(20) was codified as § 900.12(b)(14).

v. *Film masking devices (§ 900.12(b)(15) (proposed § 900.12(b)(21)))*

In this paragraph, FDA proposed that all facilities ensure the presence of film masking devices that are capable of limiting the illuminated area of the viewbox to the exposed or smaller area of the film, that facilities using nonrectangular collimation ensure suitable masking, and that such devices be available to the interpreting physicians.

(Comment 395). Six comments supported the requirement. Two of these comments further suggested that the requirement be modified to clarify that any effective means of masking, including ''black film or manual or automatic masking devices,'' would be acceptable. One comment questioned how effective the film masking devices must be because the respondent believed that many presently in use do a poor job of blocking the unnecessary light. FDA has not attempted to specify particular mechanisms for masking, only that provisions for masking be available. Any device that blocks viewbox light not required for viewing and interpreting the image would meet the intent of this requirement. The level of ''blocking'' was not addressed, but with the light levels under consideration, the agency believes that the elimination of any noticeable transmission through the masking is easily achievable. The device need not be an expensive or elaborate system, but it must be capable of eliminating extraneous viewbox light.

(Comment 396). Two comments supported the proposed requirement to provide appropriate masking for nonrectangular images as a means to further promote the correct masking of all shape images, but another comment stated that the nonrectangular collimation referenced should be eliminated because ''there is no need for it and it causes significant problems in the masking of the films for proper viewing conditions.'' NMQAAC suggested that the requirement regarding nonrectangular masking was redundant and recommended that it be removed from the final regulation.

FDA does not intend to express a preference for rectangular or nonrectangular collimation. This section was included in the proposal to reinforce the point that, in all cases, the masking should be appropriate to the image. FDA is accepting the NMQAAC recommendation and deleting the provision relating to nonrectangular collimation from the final regulations; FDA agrees with NMQAAC that the

general masking specification covers all sizes and shapes of images.

(Comment 397). One comment questioned how much limitation of the exposed image the proposal intended the masking to provide and one comment proposed that the masking requirement be expanded to require limitation of ''the illuminated area to a region or regions substantially smaller than the exposed portion of the film.''

FDA has not accepted this recommendation because it may not be desirable, in all cases, to limit the view to an area ''substantially smaller than the exposed portion of the film.'' The intent of the section is that masking be as close to the full darkened film area as possible. The masking can certainly be variable, so that the darkened area can be reduced to a specific area of interest. This is not required, however. Discussions with interpreting physicians have led FDA to conclude that it is often desirable to visualize the entire image to establish a ''gestalt'' impression before further interpretation of the film. A masking system that prevented such a practice, therefore, may be undesirable and is not being required.

(Comment 398). One comment questioned to what extent the film masking devices were required to be available. The comment asked if all mammograms were required to be read on viewboxes equipped with masking devices or if the facility need only require adequate masking for one viewbox, even if multiple reviewers were reading film at the same time on different viewboxes.

In response to this comment, FDA has modified the final regulation to indicate that such devices should be available in sufficient numbers to allow each physician requiring one to have access to one. NMQAAC recommended that the requirement that the devices be available to physicians should be deleted, stating that any physician who desired to use masking could provide their own at little or no expense and that the facility need not provide such devices for them. FDA partially agrees with this assessment but has not accepted this recommendation because it has concerns about facilities that require significant numbers of films to be read daily and where the interpreting physician simply does not have time to individually mask images. Placing responsibility with the facility will ensure that masking devices are provided in such cases.

(Comment 399). Two comments recommended that the regulation mandate the use of film masking devices by the physician, and one of these suggested that masking should be used by the technologists in their film critique area. While FDA certainly agrees that both interpreting physicians and technologists should utilize masking, the agency believes that, if the devices are available, most individuals will use them and that requiring their use would be difficult to enforce.

(Comment 400). One comment stated that film masking devices may be expensive to obtain and cumbersome to use. This comment maintained that, although film interpretation may be improved by using these devices, requiring that facilities provide such devices appears to be excessive regulation and this requirement should be deleted.

FDA notes that the goal of the MQSA is to provide a consistent baseline of quality mammography services to all patients. If an item that is consistent with that goal is identified as having a positive impact on the diagnostic process, FDA believes it is important to assure women that facilities at least have these devices available for use on their behalf. FDA also notes that masking devices do not ordinarily entail significant expense. FDA has codified the requirement for availability of masking in the final regulations under § 900.12(b)(15).

w. *Film processors (§ 900.12(b)(22) (proposed § 900.12(b)(22)))*

In this paragraph, FDA proposed a number of requirements for the film processors used to develop mammograms. As proposed, § 900.12(b)(22)(i), covering processor setup and maintenance, would go into effect 1 year after final publication; § 900.12(b)(22)(ii) and (iii), requiring display of the time cycle and maintenance of the developer temperature, would be phased-in after 5 years; and § 900.12(b)(22)(iv) and (v), requiring the display of the developer temperature and for variable cycle processors to be interlocked to prevent new film being accepted by the processor until cycle parameters are stabilized, would be phased-in after 10 years.

Section 900.12(b)(22)(i) proposed that all such processors be set up and maintained at the technical development specifications for the film used for mammography at the facility.

(Comment 401). One comment requested a definition of technical development specifications, as used in the proposed regulations. Another comment stated that, if it is going to be mandatory to meet film manufacturers technical requirements, then manufacturers should be required to make written guidelines available as to what factors are needed to achieve the maximum result from the film.

FDA coined the phrase ''technical development specifications'' to represent a listing of the technical aspects of correct processing as provided by the film manufacturer. This would be expected to include such items as correct solutions, proper temperatures, applicable immersion times, replenishment rates, and any other instructions the manufacturer deemed appropriate and critical to the processing of its film. FDA believes that many manufacturers do provide such information and that the market advantage these manufacturers will enjoy will encourage all manufacturers to do so. The NMQAAC recommended that this section be moved to the quality assurance provisions and FDA has followed that advice.

The agency has reconsidered the proposed requirements in § 900.12(b)(22)(ii), (iii), (iv), and (v). FDA received a number of comments both supporting and opposing these proposals. However, based on the anticipated costs associated with these proposals compared with the marginal benefits they would provide, FDA has decided to delete them from the final regulations. If the agency proposes future regulations for these areas, all related comments will be reconsidered.

3. Medical Records and Mammography Reports (§ 900.12(c))

This section establishes quality standards for medical records and mammography reports as required by the MQSA under 42 U.S.C. 263b(f)(1)(G). The regulation provides, in general, that facilities prepare written reports of mammography examinations, that results be communicated to the patient or provider, and that films be maintained for a reasonable period of time or transferred to the patient.

(Comment 402). Public comments were received on § 900.12(c). The most controversial areas were specific provisions in the proposal for use of standardized assessment categories in the mammography report, written notification of all mammography results, and for original mammograms to be transferred to other facilities or entities upon patient request. Each of these areas will be discussed below in connection with those specific provisions.

a. *General comments*

As an initial matter, FDA disagrees with four comments that asked FDA to delete the entire regulation on medical records and reports because it was an intrusion of FDA into the practice of medicine and abridged the rights of

radiologists. The agency's authority and responsibility to regulate these medical records, mammography reports, and communication of results was established by Congress through specific provisions of the MQSA. The agency could not eliminate the entire regulation, even if it believed such action was appropriate. Discussions with NMQAAC clearly indicated the committee's support for regulations in this area as well.

b. *Contents and terminology (§ 900.12(c)(1))*

The proposal established standardized assessment categories for interpreting physicians to use to evaluate mammograms, ranging from ''negative'' to ''highly suggestive of malignancy.'' In addition, the regulation requires the interpreting physician to address clinical questions, if possible, and include recommendations, if any, in the report.

(Comment 403). Comments in support of the proposed standardized assessment categories stated that such categories: would ensure that a definitive result for each mammogram is reached; would establish consistency across facilities; are a valuable tool to assist consumers and clinicians in understanding results; should also be used in the written notification to patients; and permit efficient and uniform analysis of outcomes in medical audits. One comment in support of this section suggested that the title be changed to ''Contents, terminology and timeframes.''

Fourteen comments stated that it is inappropriate for the Federal government to establish medical terms for classification of mammography results through regulation. Other comments opposing the establishment of standard assessment categories stated that: Such categories would prevent any particular facility from continuing to use its customary terminology and, thereby, cause confusion to its referring physicians; the message, rather than the exact words, are important and resources would be wasted in monitoring the correct use of particular phrases; and that establishing standard classifications would reduce flexibility for the reporting physicians.

Some comments objected to the details of a particular classification category, rather than to the idea of standard classifications. One comment stated that a ''negative'' report may mislead a referring physician about the existence of breast cancer because mammography cannot detect all breast cancers, while another comment concluded that the term ''suspicious'' inherently suggests that the lesion is malignant, and proposed ''indeterminate'' as a substitute category.

After considering all these comments, FDA has decided to keep the proposed categories in order to promote consistency and clarity in mammography interpretations. In discussions with NMQAAC, the use of final assessment categories was supported because they promote consistency in communication of results among medical care providers and standard categories are necessary in the medical audit of mammography interpretation. These particular categories are based on similar categories developed by ACR. The ACR Breast Imaging Reporting and Data System categories are: Assessment Is Incomplete-Need Additional Imaging Evaluation; 1-Negative; 2-Benign Finding; 3-Probably Benign Finding—Short Interval FollowUp Suggested; 4-Suspicious Abnormality—Biopsy Should Be Considered; and 5-Highly Suggestive of Malignancy—Appropriate Action Should be Taken.

FDA believes that the medical community is familiar with these categories and the assessment classifications established under the final regulations (''negative,'' ''benign,'' ''probably benign,'' ''suspicious,'' ''highly suggestive of malignancy'') are equivalent to the ACR system. The medical community has already affirmed their usefulness and value through widespread use of the ACR system. Accordingly, the agency concludes that requiring these classification terms in mammography reports will not be burdensome, given their current level of use and acceptance.

FDA has made minor changes in particular assessment categories in response to comments. Two comments requested FDA to delete the word ''imaging'' from the proposed assessment category of ''needs additional imaging evaluation'' and substitute the ACR category of ''needs additional evaluation'' because physical examination may be part of further evaluation. In fact, the ACR category is ''Need Additional Imaging Evaluation,'' with ''incomplete'' as its descriptor. Accordingly, FDA is adding the word ''incomplete'' to the description of this category, which will now read: ''Incomplete: needs additional imaging evaluation.'' The mammographic result should be categorized into this or one of the other assessment categories. The agency notes that, if the result is ''negative'' or ''probably benign'' based on the mammogram, but physical examination is recommended, the recommendation for clinical followup, surgical consultation, biopsy, or other action should be stated in the recommendations section of the report. The agency also is aware that there are screening mammography practices that do not issue a final assessment until followup diagnostic mammography has been scheduled and performed. These facilities, and others, can continue their policy of not issuing an assessment, and can use this category of ''Incomplete: needs additional imaging evaluation.''

FDA's proposed language for the ''negative'' category stated that if the interpreting physician is aware of clinical findings or symptoms, these should be explained. One comment asked if this explanation must be written into the report or could be attached as a symptom in-take form. The agency believes that the recommendations section of the report is the most effective way to direct referring health care providers to further work-up based on physical findings or symptoms, despite negative mammographic results.

(Comment 404). One comment stated that it would be hard to determine compliance with the proposed requirement that clinical questions raised by the referring health care provider be addressed in the recommendation section of the report.

FDA responds that it can determine compliance with a regulation in a variety of ways, including review during an inspection of a facility's standard operating procedures. FDA inspectors can be trained to verify that each facility has in place a system that requires its interpreting physicians to address the concerns of referring health care providers in the recommendations section of the mammography report. FDA agrees with comments that suggested that the recommendation section of the report remain separate and unstructured; the agency has not proposed specific categories or language for this portion of the report in order to provide maximum flexibility for clinical management recommendations.

(Comment 405). One comment stated that there should be a unique patient identifier to distinguish between two patients with the same first and last name. NMQAAC also agreed, stating that the medical report and the mammography films should have a patient identifier in addition to the name. FDA agrees that an additional patient identifier in addition to the name will improve the accuracy and clarity of the results and subsequent followup and the proposal has been amended to require reports to have this additional identifier. However, the

choice of the additional identifier, such as the date of birth or hospital number, is left up to the facility because each individual practice has a better understanding of its particular needs in this matter.

(Comment 406). Two comments asked if a radiologist who did not read the film or dictate the report can sign a report if the radiologist who did perform the interpretation is unavailable and concurs with this practice. Another comment stated that FDA should allow signatures that are authenticated through computers, which are normally accepted in a court of law. A third comment stated that signatures should be evident on the report filed in the patient's permanent file.

FDA interprets the MQSA's requirement that each mammography report be ''signed'' by the interpreting physician to mean that each report must identify who interpreted the mammogram and rendered the reading on the written report. The final regulations state that the name of the interpreting physician must be on the mammography medical report. This name may be handwritten, typed, stamped, written electronically, or recorded in any other manner. However, with respect to ''signatures'' that are used to proof-read reports or to ''sign'' them out for purposes of authenticating such reports or releasing them to other parties or institutions, FDA believes that each facility is in the best position to devise its own procedures to ensure accuracy of reports and integrity of the system without the MQSA regulations in this area.

(Comment 407). One comment recommended that there be a requirement for facilities to maintain records that include the signature of the qualified radiologic technologist who performed or supervised the examination and the signature of any individual who conducted all or part of the examination under supervision of a qualified radiologic technologist.

FDA disagrees with this comment. The MQSA does not have a signature requirement for the technologist. The final regulations require ''technologist identification'' on each film image (§ 900.4(c)(viii)(E)) and the agency believes each facility can adopt its own system to identify technologists without having the agency mandate such procedures.

(Comment 408). One comment suggested that the term ''health care provider'' should be replaced with ''referring physician.'' FDA disagrees because patients are referred for mammograms by nonphysicians, such as physician's assistants, nurse practitioners, and other health care workers.

c. *Communication of mammography results to patients (§ 900.12(c)(2))*

This provision requires that: (1) Each facility establish a system to ensure that results are communicated to patients; (2) patients without health care providers receive medical reports and lay summaries of their mammography results; (3) each facility establish a referral system for patients without health care providers, if necessary; and (4) results that are ''suspicious'' or ''highly suggestive of malignancy'' be communicated as soon as possible.

(Comment 409). FDA received hundreds of comments on the proposal that all patients receive written results of their mammography examination. Comments that objected to this proposal generally focused on disruption of doctor-patient relationships, confusion for patients, and additional expense to facilities without commensurate patient benefit. Ninety comments stated that the referring health care provider is responsible for communicating results to patients and is best able to convey such results and answer patient questions. Other comments that raised concerns about disrupting the referring doctor-patient relationship stated that written notification from the facility would allow patients to bypass a referring physician and never get a physical breast examination. Many comments stated that written notification to every patient would cause confusion for the patients. Twenty-three comments said confusion would arise if patients were notified about results before such results were reviewed by their referring physicians; twenty-one comments stated that many patients would misinterpret their reports; ten comments stated that the difference between the information provided in a lay notification and the information contained in a copy of the actual written report would confuse patients who received both.

Seventy-two comments stated that the additional cost associated with written communication to every patient would cause financial hardship for mammography facilities. In general, these comments and others argued that the cost of providing or ensuring written notification in every case outweighs any patient benefit that might result. Ten comments stated that radiologists would have to police referring physicians who agreed to provide patient notifications and followup. Other comments stated that: (1) Small or rural facilities would be burdened by patient notification requirements, especially those without a computerized system; (2) producing patient notification reports is time-consuming and hinders the accomplishment of daily operations, and would not directly improve patient care; (3) developing a notification document that could explain every possible scenario involving diagnostic findings is virtually impossible; and (4) radiologists and providers of mammography would become more frequent targets of litigation because of this reporting requirement. Thirty-seven comments stated that it is unrealistic to expect radiologists, who may never see patients, to determine the literacy level, ethnic, cultural, and social sensibilities of those patients in order to tailor an appropriate written notification. Fifteen comments stated that the requirement would create excessive waste paper for the environment. Some comments found the proposal for written notification unnecessary in light of other reporting and followup requirements, the individual patient's responsibility to communicate with her physician, and the belief that patients are always informed of results by their physicians. Two comments asserted that written notification for all patients was not authorized by the MQSA.

FDA also received 66 comments that supported the proposal for all patients to receive written notification of mammography results including comments offering strong support from national breast cancer patient groups. These comments generally focused on the fact that women otherwise were not assured of timely and accurate information about their mammography examinations and that such written notification could save lives by encouraging initiation of necessary followup.

It was also noted that the experience of facilities that instituted such notification was positive. Comments in support of written patient notification stated that such notification was appropriate because patients are entitled to know the results of their exams, it is the facility's responsibility to inform patients of results, and there is a public health need for written notification because not all referring physicians discuss results with their patients.

(Comment 410). Comments described written notification as an important addition to quality mammography practice, a crucial component to ensuring reliable mammography and consistency across the country, and a major step toward fostering better communication between doctors and their patients. One comment supported the proposed system to ensure that patients and referring physicians receive reports, and that all patients receive a

report in lay terms, but also stated that the referring physician should continue to be responsible for patient followup. Another comment stated that FDA should not allow any party, other than the facility, to distribute these written notifications.

Many comments asserted that written notification for each patient may ultimately reduce health care costs and extend lives because of earlier treatment. Five comments stated that written notification empowers the medical consumer and minimizes the possibility of tragic error when abnormal results slip through the cracks of the referring physician systems. Comments asserted that referring physicians do not always communicate results to patients, even when the results are abnormal. Several breast cancer survivors commented positively on this proposed requirement and one author stated that such written notification saved her life. Seven comments stated written notification has reduced medical liability of facilities, but that costs should be offset with increased reimbursement.

Comments from State health officials and some facilities having experience with written patient notification reported that the experience had been positive. Facilities that have instituted written notification stated that the practice is appreciated by patients and does not cause the facility any particular hardship. Massachusetts has required such written notification since 1994. The comment from a State official stated that, although initially resisted, the procedure is now accepted by physicians throughout the State; facilities in Massachusetts receive positive feedback from patients and no facility has closed in that State because of this additional requirement.

Some comments recommended that the notification include additional information. Twelve comments asked that the written notification also include information about the location of the films, directions about how a woman could obtain them, and the facility contact person for questions concerning the result. Another comment said the notification should include information about the importance of clinical breast examinations by a qualified physician, monthly self-breast examinations, and mammograms at appropriate times, especially for patients without physicians. Some comments wanted facilities to be required to provide written notification to referring physicians and patients.

Many comments suggested alternatives that were variations to the proposed requirement for written patient notification. Ten comments supported the current interim regulations, which require written notification from the facility only to those patients who do not have a health care provider or referring physician. Thirteen comments stated that, for referred patients, the required notification should simply state that the mammogram report has been mailed to the physician and the examinee should contact that physician. Twelve comments stated that only those patients who request a written report should be sent one.

Other comments agreed that patient notification of results by the facility was appropriate, but preferred to leave the method of communication up to the facility, which could tailor notification procedures to its practices and the circumstances of particular patients. Comments observed that in some screening cases, where the radiologist never speaks to the patient, written notification of results makes sense; however, where there is extensive interaction and verbal communication with the examinee onsite, written notification can be redundant, expensive, and wasteful of paper. Five comments stated that patients should be verbally told at the time of the examination to contact her physician's office and not to assume that ''no news is good news.'' Other alternatives suggested by comments included several that were in direct contradiction to each other: (1) Require written notification only to those patients who have not received the final report verbally at the facility or, if findings are negative, by telephone; (2) encourage notification of patients with abnormal studies; (3) require patient notification in lay terms only if the results are negative and notify referring physicians, including followup notes, when there are abnormal results; (4) send referring physicians lists of patients who had mammography at a facility with positive studies highlighted; (5) require notification of patients who request results after a specified time period has passed in order to allow communication between the patient and the referring physician and to prevent duplication and failure to inform; and (6) require that every patient receive a copy of her mammography report, if desired, or by default if her preference is not stated.

After reviewing and considering the hundreds of comments FDA received concerning patient notification, the agency concluded that these many comments all share the common goal of providing an effective mechanism for communicating mammography results to patients, but that the comments clearly advocate different approaches to achieving this goal. FDA agrees with consumer groups that written notification of mammographic results represents ''best practices'' in ensuring that each and every woman is clearly and effectively notified of the results of her mammogram. These ''best practices'' are outlined clearly in a series of recommendations published by AHCPR in Chapter 4 of the 1994 guidelines entitled, ''Quality Determinants of Mammography'' (Ref. 2). In these guidelines AHCPR strongly recommends that mammography facility personnel provide each patient with written notification of the results of her mammography examination either onsite or by mail. Studies cited by AHCPR have shown that direct communication with patients, which is in addition to written communication to health care providers, dramatically increases compliance with followup recommendations. However, FDA also recognizes that many in the health care community have strong reservations, for the many reasons cited above, about making written notification to all patients a Federal requirement. Finally, FDA notes that although the MQSA requires mammography facilities to notify patients' referring physicians, in writing, of the examination results, the statute requires those facilities to notify patients directly in writing, only in those instances where the patient has no referring physician. FDA believes that the best way to reconcile the many different points of view on this subject—and achieve the goal of effective patient notification consistent with the statute—is to issue a general rule requiring patient notification, together with a recommendation that facilities follow the AHCPR guidelines regarding written notifications to patients. The relevant portions of the AHCPR guidelines have been printed as an appendix to the preamble of this document for ease of reference.

Accordingly, the agency has revised the final rule to eliminate the requirement for written notification to every patient and has substituted a performance-based regulation that requires each facility to ensure that the results of each mammographic examination are communicated to the patient. Under the final rule, each facility will be responsible for establishing a system of notification, through its own efforts or in cooperation with third parties, that guarantees that patients are informed of the results of their examinations in a timely manner. The system must also ensure that women who do not have health care

providers receive written notification, along with the mammography medical report, no later than 30 days following an examination and that each facility communicate abnormal results as soon as possible.

As noted above, FDA continues to believe that written notification of mammographic results is the most reliable way to guarantee that each patient is notified of results and that any necessary followup will occur. Comments from consumer groups and breast cancer survivors about the importance of early and accurate communication to patients supports the public health need for systems that ensure patient notification. Written notification to a patient of results can permit that patient to make informed medical decisions at critical times. One cancer survivor informed the agency that having the actual results of an abnormal study in hand allowed her to pursue treatment options that saved her life. Furthermore, the agency disagrees with comments that assume all patients are notified of their mammographic results; many referring health care providers do not communicate results of mammograms to patients and the adage ''no news is good news'' still rings true for many patients. During the MQSA inspections, FDA has uncovered a handful of facilities that do not even issue written mammography reports to referring physicians. Accordingly, the agency is continuing to require each facility to establish systems that will ensure that patients are notified of the results of their mammograms.

FDA believes that high quality mammography extends from the production of high quality mammographic images to the communication of results to the patient. Ensuring that patients get their results is the responsibility of all participants in the mammography imaging chain: The patient, the facility, and the referring health care provider. The final regulations fully charge facilities to meet their responsibility.

At its January 1997 meeting, NMQAAC recommended that all facilities should not be required to provide written notification. While some concern was voiced about difficulties in directly notifying all patients who underwent diagnostic mammography, many members advised FDA to require some type of direct notification of all patients and that this notification be documented. Although the agency continues to support written notification to all patients as the optimum practice under most circumstances, the final regulation does not prescribe any particular form of notification. Comments from facilities and physicians indicate that facilities have devised a variety of systems of communication to notify patients of mammography results. These include verbal conversations at the time of the examination, telephone communication after the examination, cooperative arrangements with referring physicians who convey the results verbally to their own patients, and written communications that are either directly issued from the facility and convey results or instruct the referring physicians to issue these reports. The AHCPR guidelines recommending direct written communication to all patients also provided examples and suggestions about the other types of communication.

Under the final regulation, in the case where a facility decides to rely on a third party to communicate results (either written or verbally), there should be a documented agreement between the facility and the third party that establishes this cooperative responsibility. This documentation may be in the form of attestation by the third party or letters of agreement signed by the third party. In addition, the agency reserves the right during inspections to confirm not only the presence of such documentation, but also to ask for further documentation from the facility to verify that patients were indeed notified. Further documentation can include copies of referring physician medical records documenting that results were discussed or sent to the patient. These descriptions of systems and documentation are intended to be examples; others may also be acceptable. However, if third parties do not provide the mammography facility with further documentation when requested during inspections, the mammography facility is subject to regulatory enforcement action under the MQSA for failing to document that results were provided to patients. Thus, for facilities that choose to rely on third parties for communicating results, whether they be referring physicians or communication consultants or other parties, the facility still has ultimate responsibility to meet the patient notification requirements of the final regulations.

The agency also believes that the approach taken in the final regulation will address the concerns about communication and cost that were raised by so many of the comments. The flexibility that has been built into the final regulation will permit facilities to tailor notification systems to the particular needs of the general patient population and individual patients they serve. At the same time, requiring each facility to establish and document the existence and operation of such systems achieves the primary goal of ensuring that patients receive the results of their mammograms.

In addition, the agency notes that the requirement for reasonable attempts at immediate communication when results of an examination are ''suspicious'' or ''highly suggestive of malignancy'' has been retained in the final regulation. Potential delays in diagnosing and treating breast cancer are reduced with this requirement that facilities directly notify patients who have no health care provider of abnormal results as soon as possible. (The same requirement for immediate communication in the case of ''suspicious'' or ''highly suggestive of malignancy'' findings applies to the facility's communication with the referring physicians of those women who have identified health care providers). The agency concludes, therefore, that the most significant public health risk that may result from failure to communicate results is addressed in the final regulation.

The final regulation continues to require written notification by facilities to patients who do not have referring physicians, as specified in the MQSA. The statute also sets forth, and the regulation incorporates, the requirement that such self-referred patients receive a copy of the actual mammography report that would be prepared and sent to the referring physician, if there were one. In response to comments that questioned the agency's authority to require patient notification, FDA notes that the language of the MQSA is very explicit with respect to patient notification of test results and the form that notification must take in these particular circumstances (see 42 U.S.C. 263b(f)(1)(G)).

(Comment 411). Many comments urged FDA to require referring physicians to be responsible for the communication and followup of results of mammography examinations. FDA agrees that a physician with knowledge of a particular patient's entire medical history is often the best source of communication and followup of results. However, FDA's primary jurisdiction under the MQSA is related to mammography facilities and not individual practices of referring health care providers.

One comment suggested an arrangement whereby facilities and each provider of care enter into a written agreement that the referring physician assumes responsibility and liability for informing his or her patients of mammography results, and the mammography facility would be

allowed to breach this contract at any time when a patient requests the results in writing. FDA agrees that this arrangement would meet the requirements of the final regulations. However, if referring physicians fail to communicate results to patients despite their agreement to do so, the mammography facility is responsible under the MQSA for failing to ensure communication of results and is subject to regulatory action by FDA.

FDA intends to look for documentation during inspections to establish that patient notification systems are in place and operational. For example, if a verbal communication system is used to tell patients of results, this communication should be documented in the patient's medical record and should be capable of verification by the MQSA inspectors. If a facility sends letters to patients, records of that correspondence, or standard operating procedures describing this correspondence, must be available for inspection. In circumstances where a facility relies on referring physicians or other third parties to communicate results to patients, the facility must provide documentation of these arrangement and their implementation, as described above. In those cases where the mammography facility is the primary breast care provider for the patient, there must be documentation of results being conveyed to the patients. By allowing a variety of notification systems, the agency has attempted to ensure that communication of results will be accomplished effectively, but without undue burden on mammography practices or unnecessary increases in the cost of mammography services. Finally, the agency notes that the regulations being issued to require facilities to establish and maintain systems that ensure patient notification of results does not preclude any patient from requesting additional reports or records from the facility. Nothing in the record and report section of the MQSA should be construed to limit a patient's access to the patient's medical records (42 U.S.C. 263b(f)(1)).

(Comment 412). One comment stated that FDA's intention to inspect and monitor systems established by facilities to verify that patients receive notification of results in lay language is unrealistic and that facilities should not be required to establish such systems.

FDA disagrees. FDA has issued interim regulations, as required by the MQSA, that required notices in lay language to be issued, along with the actual report when patients do not have a referring health care provider (42 U.S.C. 263b(f)(1)(G)(ii)(IV)). This is a current requirement for all facilities and is already subject to inspection and verification.

(Comment 413). One comment stated that complex situations, such as when a mammogram is assessed as negative, but the patient has clinical findings, need careful explanation to patients so that the importance of the situation and recommendation for followup will be understood. This comment recommended that the mammography facility be responsible for patient care if it is accepting women who have no physicians.

FDA believes this practice standard is largely being adopted by the mammography community and supports this. Under the final regulations, each facility is required to maintain a system for referring patients to health care providers when clinical followup is recommended and the patient has no physician.

(Comment 414). One comment stated that followup reminder letters are critical and should be mandated.

FDA disagrees that these should be mandated. Rather, each practice should be allowed to determine if such letters or other forms of reminders are needed.

(Comment 415). One comment reflected confusion about the immediate followup call to patients required under § 900.12(c)(2), which is in addition to the notification requirements. Although notification is required for all patients under the system established by the facility to ensure such communication, FDA believes that special efforts at communication are required when there are abnormal results and the patient does not have a referring physician. In these cases, the facility is expected to contact the patient who has no health care provider as soon as possible and the 30-day timeframe for sending reports and long summaries is superseded. Under the final regulations, this immediate communication is required only in situations where the probability of cancer is high (mammograms assessed as ''suspicious'' or ''highly suggestive of malignancy''). In cases where such immediate notification is required, the facility remains obligated to also provide the necessary written notifications within 30 days as followup.

(Comment 416). One comment supported the requirement that, when an examination shows suspicious findings, a facility should directly communicate with a nonreferred patient. This provides patents the assurance that they will receive the care they need.

FDA agrees and the final regulations contain this requirement.

(Comment 417). One comment stated that, in cases where assessments are ''suspicious'' or ''highly suggestive of malignancy'' and results must be ''immediately'' communicated to the examinee or physician, FDA should define what ''immediately'' means. Another comment suggested ''immediately'' be defined as 24 hours.

FDA believes that the variety of circumstances that may arise when followup is required make a rigid definition of ''immediate'' unreasonable. Because there are circumstances when immediate communication is not possible, FDA has revised the requirement to communicate abnormal results from ''immediately'' to ''as soon as possible.'' Health care professionals understand the importance of accomplishing such notification when there are suspicious or highly suggestive findings. Although it is impossible to establish a precise timeframe, FDA expects such communication ordinarily can be accomplished within 48 to 72 hours and not later than a week following the examination.

(Comment 418). One comment stated that 30 days is an unreasonably long window in which to notify patients of results. Three other comments agreed with FDA that 30 days was reasonable. Another comment stated that reports and notification should not be sent out for at least 5 days in order to wait for outside comparison films; otherwise, addenda lay notification and reports would confuse patients and physicians. Another comment recommended that notification to patients should wait until all mammography imaging work up has been completed.

FDA believes that issuing medical reports to health care providers (or to patients with no health care providers along with lay summaries) within 30 days is a reasonable standard. This does not mean facilities must wait 30 days, as the first comment suggests, but rather that 30 days is the outside limit. FDA disagrees that notification of results should be delayed until the total imaging work-up is completed because situations arise when imaging work-ups can extend over more than 1 month. Therefore, FDA is requiring a report of the medical finding for each mammogram to be generated within 30 days. Under the final regulations, facilities must also ensure that patients have their results communicated to them within that time. Many facilities may notify patients or have other parties notify patients after written medical reports are provided to physicians; other facilities may choose to communicate

results to patients prior to the issuance of the medical report to the referring provider by means such as providing verbal results at the time of the mammography examination. As discussed above, a variety of systems will be acceptable as long as they ensure that results are communicated to patients and that communication is timely.

(Comment 419). Eight comments stated that patients without health care providers should not get the actual medical report along with the lay notification. These comments claimed that the terminology in the medical reports would confuse patients and either generate more inquiries or keep them from understanding that further studies are needed. They recommended instead, that patients can request the report be sent to a physician if further medical advice is desired. One comment also stated that, while it is critical to include the patient in the information loop for the results of her mammogram, it is poor medicine to send the patient who is self-referred the copy of the mammogram report that is intended for the physician.

FDA disagrees. The MQSA expressly requires facilities to provide patients without referring physicians both the medical report and the lay summary (42 U.S.C. 263b(f)(1)(G)(ii)). This requirement allows the patient to provide her mammography report immediately to a subsequent health care provider, if needed.

(Comment 420). Two comments asked what is meant by ''reasonable attempts'' to communicate results of suspicious studies to patients without referring physicians as soon as possible. The comments asked whether a certain number of phone calls or a registered letter would be acceptable.

FDA does not intend to mandate procedures for communication with patients in these circumstances because different methods are likely to be more or less effective with different facilities and patient populations. Telephone calls and registered mail are examples of attempts at communication that may work. Verification that contact has been made is the goal. Each facility can consult with its risk management director to establish procedures to convey results and document attempts at communication that are ''reasonable.'' FDA recommends that mammography facilities utilize the AHCPR's guidelines in ''Quality Determinants of Mammography'' that address the effective communication of mammography results to patients and follow those guidelines with respect to written notification to patients. That document includes excellent sample lay notices that facilities could adopt. As noted previously, information from Chapter 4 of these guidelines has been reprinted as an appendix to the preamble of this document for ease of reference.

d. *Communication of mammography results to health care providers (§ 900.12(c)(3))*

The final regulation requires each facility to provide the mammography report to a referring or named health provider within 30 days of the date of the examination. The regulation also requires a facility to make reasonable attempts to communicate with the health care provider or the provider's designee as soon as possible when an examination reveals suspicious results. These requirements paralleled those for communication of suspicious results to patients without identified health care providers.

(Comment 421). Five comments requested guidance in defining who is a responsible designee of the health care provider.

In response, the agency notes that when referring health care providers are not available, they ordinarily have responsible designees, such as medical coverage services or partners, to assume medical responsibilities for the unavailable provider's patients. These requirements parallel and complement those related to patient notification.

(Comment 422). Twenty-nine comments stated that 30 days is a reasonable time period for getting reports out (unless there are delays in obtaining comparison studies). Three comments asked FDA to define the timeframe required for ''immediately'' communicating the results of suspicious or highly suggestive mammograms to health care providers. One comment expressed concern that the requirement to attempt to communicate ''suspicious'' or ''highly suspicious of malignancy'' findings to health care providers immediately will impose an unmanageable burden on understaffed facilities.

FDA disagrees with this last comment but, as with the provision relating to communication with patients, the agency has changed the language from ''immediate'' to ''as soon as possible'' because immediate communication may not be possible given the variety of circumstances that may be associated with communication of suspicious results to a particular provider. FDA believes health professionals understand the urgency of the situation when a patient has a suspicious or highly suggestive mammogram and they are mandated to communicate this result to the referring health care provider in an attempt to expedite diagnosis or treatment. Again, although it is not realistic to mandate a rigid schedule, the agency expects that such communication ordinarily can occur within 48–72 hours, and not later than a week following the evaluation of the examination. NMQAAC discussed this section and supported the regulations as revised.

(Comment 423). One comment questioned the ability of physicians who read only twice a week to comply with the requirement to communicate with health care providers within the mandated timeframes. FDA believes timeframes and procedures are sufficiently flexible to balance the need to protect patient health with the realities of good mammography practices. Reading twice a week does not preclude a physician or the facility that employs that physician from complying with the requirements.

(Comment 424). Another comment recommended that radiological reports transmitted to the referring physician be acknowledged by electronic signature, which should be kept in the electronic file indefinitely. As stated previously, with respect to proof-reading reports and ''signing'' them out (for authentification or release), FDA assumes that facilities are able to devise their own procedures to ensure accuracy of reports and integrity of the system without the MQSA regulations at this time.

e. *Recordkeeping (§ 900.12(c)(4))*

FDA's final regulation implementing recordkeeping standards for facilities requires each facility to maintain films and reports at least 5 years or until the patient requests them or requests their transfer. If the film and report represent the only mammogram for that patient, the facility must retain them for 10 years or for any longer period of time that is required by State law or until the patient requests them or requests their transfer.

FDA received numerous comments supporting its proposal to require transfer of the original mammogram upon the request of the patient.

(Comment 425). Fourteen comments stated that original films should be transferred because copies are frequently poor quality and jeopardize successful followup. Four comments stated that the request for transfer should be in writing and that the regulation should state ''temporary or permanent transfer.''

FDA believes each facility should be free to establish its own procedures for transfer of films and may wish to consult its risk management director for

guidance. FDA agrees in part with the last comment and has modified the final regulation to clarify that a patient may request that the transfer of the original films be temporary or permanent. FDA will leave it to the facility to decide whether the request for transfer should be in writing or may take some other form. NMQAAC also supported the addition of this language to the final regulation.

The agency has also amended the language of the provision to clarify that a request for a transfer supersedes a facility's responsibility to maintain the films for a particular length of time and that the request may be made by an individual on behalf of the patient as, for example, might be necessary in cases where the patient is incapacitated or has a legal guardian.

(Comment 426). Two comments agreed that original mammograms should be sent for comparison to other facilities. However, these comments stated that FDA's suggestion in the preamble to the proposal that facilities make a copy is very difficult and expensive. Another comment stated that copying originals to retain in the record when transfer is requested should not be required because this would increase costs, would not be adequate for comparisons, and would delay sending films out in the timely manner.

In response to these comments, the agency notes that there are no requirements for facilities to make copies of films they are requested to transfer. If this suggestion to make and keep a copy of the mammograms is not practical or useful to a facility, it need not be followed.

(Comment 427). Three comments supported the transfer of original films, but would require their return within 30 days in cases of temporary transfer.

FDA does not intend to establish a time limit on transfer of films at the request of patients. Even in cases where the transfer is temporary, the originals may be used during clinical procedures that may not be completed in 30 days. However, FDA does support the return of films in a timely manner and expects facilities that transfer and receive films under such circumstances to cooperate in the interest of the patient's treatment.

(Comment 428). FDA also received many comments expressing concerns about original film transfers. Twenty-six comments stated that transferring original films is problematic because the films may be lost, their transfer may breach confidentiality, the originating institution will not be able to make comparisons, and patient may be denied access to films at a later date. One comment stated that FDA should clarify if the transfer of original films conflicts with State or locals laws and how facilities should proceed if that is the case. Four comments urged FDA to delete the proposal because the films themselves are historically the property of the physician or institution which generated them and their absence would disadvantage those physicians or institutions in defending against claims asserted against them. Fourteen comments asked if FDA will indemnify the radiologist for not having original films in the event of a malpractice action. One comment stated that there is no enforcement provision against those facilities who refuse to release original mammography studies on the grounds of ownership or the potential for legal action.

FDA understands that the transfer of original films has not been a universal practice among facilities and that physicians may have concerns about the consequences of loss or misplacement. Nevertheless, the agency has concluded that the overwhelming benefit to patients from access to original films by other facilities or physicians providing followup for patients justifies the need for this provision in the final rule.

All expert comments FDA received on this matter, including advice from NMQAAC, emphasized the value of having original films for comparison to subsequent studies or followup clinical procedures. There was general agreement that copies of mammograms could not adequately substitute for originals when difficult diagnoses or additional procedures were required, and that clinical decisions, such as whether to do surgery, require review of original films. The agency notes that even those practitioners who criticized the proposal agreed that the transfer of films was likely to enhance patient care. Those who objected did so on grounds that were unrelated to patient care, namely potential for liability and difficulty in defending malpractice actions.

FDA has not been persuaded that these concerns are insurmountable or that they are sufficient to override the public health benefits associated with the provision.

Many facilities do routinely transfer films upon the request of patients and have established procedures and systems to implement that process. Those procedures may include written requests from patients, release forms that establish transfer of responsibility for the films, and agreements with receiving institutions for subsequent return. In some cases, facilities that transfer films do make and retain copies for their own files; other facilities have determined that the expense of copying is not warranted. Loss of films will not be indemnified by FDA.

With respect to facility concerns about defense of malpractice claims, FDA notes that rules of evidence, including civil discovery, establish judicial procedures that are designed to protect each party's ability to develop its case. Judges have authority and discretion to craft remedies in situations where a patient has lost, withheld, or is resisting production or examination of a necessary original record.

FDA is not aware of any State laws that conflict with the requirement that original films be transferred upon the patient's request. State laws governing the management and retention of medical records appear to be silent about the transfer of original films. Rather, they are likely to state that patients are entitled to copies of their records or that doctors are required to maintain records. This was the case with the Florida and New York laws that were brought to the attention of the agency.

Were a State to enact a law that conflicts with this regulation or if, contrary to FDA's understanding, such laws currently do exist, those State laws would be preempted. The agency disagrees with comments that have inferred such laws would be permissible under the provision of the MQSA that allows States to establish more stringent requirements relating to mammography (42 U.S.C. 263b(m)). The public policy considerations underlying any State laws that would restrict a patient's access to original films and the quality data that may only be available from these original studies would not be related to the public health objectives of the MQSA. Accordingly, such State laws could not be characterized as more stringent than the MQSA or this regulation. The agency also notes that the records provision of the MQSA that is being implemented by this regulation explicitly states that nothing in that provision shall be construed to limit a patient's access to that patient's medical records (42 U.S.C. 263b(f)(1)(G)).

(Comment 429). One comment recommended that FDA add that, upon receipt of authorization to release mammography film, the mammography facility must forward the films to the requestor in a reasonable timeframe to minimize reporting delays. Another comment suggested that each facility be required to provide original films and copies of reports within 10 working days of receipt of a written request.

FDA does not believe it is necessary or useful to mandate the details of such transfers. The agency believes that each

facility will develop standard operating procedures to implement this standard and that those procedures will reflect the controls required by risk management and acceptable practice standards.

(Comment 430). Six comments suggested that the facility that took the most recent mammogram should maintain ownership of all the originals because this practice would make it easier to keep the films available for future comparisons. FDA's final regulations do not preclude this arrangement if the patient requests transfer of previous films to the current facility.

(Comment 431). Twenty-four comments asked who should bear the cost of copying films when the original is released. One comment stated that facilities should only be able to charge a nominal fee for transfer of films and reports. Another comment believed that the fees must be closely monitored; the comment noted that reports have been received in the past from facilities charging unreasonably high fees for sending reports and copies of mammography films. A third comment stated that FDA should develop fee guidelines for charges for copying film and postage to prevent some institutions from charging high fees.

FDA generally agrees with these comments and its final regulations limit charges to the documented cost of the transfer, so as to not deter patients from requesting transfers when necessary. The agency notes that nothing in the regulations requires facilities to charge fees for transfer of records. If copies are made as part of the facility's standard transfer process, then the cost of copies may be documented and included in the transfer fee charged by the facility.

(Comment 432). One comment asked if the fee can include a storage charge or is it for medical records transfer only.

The regulations clearly state that any fee is for services provided under § 900.12(c)(4)(ii), which is the transfer of films and reports.

(Comment 433). Twelve comments stated that the proposal that fees charged for transfer of films and records not exceed costs appears to be price controls, if not price fixing.

The agency does not agree that it has taken any action to establish prices. FDA is responding to complaints that fees charged for transfers of records have been unreasonable. This practice prevents consumers from making such transfers and obtaining medical care with the best quality medical data. The regulation does intend to control such charges in order to ensure access by patients to their films but the final rule does not require facilities to absorb additional expenses. Instead, each facility that decides to charge consumers for this service must limit its charges to documented costs.

(Comment 434). Nine comments stated that original mammograms should be provided by other facilities for comparison purposes free of charge as a courtesy among institutions.

FDA supports this process; the final regulations do not mandate a charge. However, if any fee is established, FDA's regulation requires that it not exceed costs of transfers of such records.

(Comment 435). Two comments suggested that FDA's regulations should consider future technology, which may include the electronic transfer of films.

FDA regulations are for screen-film and xeromammography. As other technology is approved for medical use, alternative standards under the MQSA will be issued.

(Comment 436). One comment asked if a facility must retain a series of mammography records for 10 years and discard them as each record is 10 years old, or discard them when the oldest record is 10 years old. FDA interprets the provision in the MQSA to mean that, if there is a series of mammograms for a patient, the oldest mammogram of the series can be 5 years old. If there is only one mammogram for a patient, it must be kept 10 years unless a transfer is requested. One comment stated that mammograms should be maintained for longer than 10 years if mandated by State or local law. In fact, the MQSA mandates this and FDA has written its regulations to conform to this provision.

(Comment 437). Two comments recommended that mammograms be kept indefinitely in order to spare a patient an unnecessary biopsy and another comment recommended that FDA establish a standard retention period of 5 to 7 years.

The final regulations do not preclude facilities from keeping mammograms longer than what is required by the statute as a minimum. However, the agency rejects the 5 to 7 year standard because the timeframes set forth in the regulation are prescribed by the statute.

(Comment 438). One comment recommended that FDA reinstate a HCFA requirement that previous mammograms be obtained for comparison with present films.

FDA believes that this is good medical practice, but it is not an appropriate focus for FDA regulations under the MQSA.

f. *Mammographic image identification (§ 900.12(c)(5))*

This provision describes the elements that must be included on any mammography film to identify the image. They are: patient identifier, date of examination, view, laterality, facility identification, technologist identification, cassette/screen identification, and unit identification, if the facility has more than one unit.

The NMQAAC advised FDA that these elements need to be present on all mammogram films to ensure proper patient care. FDA agrees. These are the same elements as those established by § 900.4(c)(2)(viii) to identify films submitted to accreditation bodies for clinical image review. Comments received from the public relating to these elements for film identification are addressed in that section of the preamble that discusses § 900.4(c)(2)(viii).

4. Quality Assurance—General (§ 900.12(d))

This paragraph was intended to identify the individuals responsible for the actions required by § 900.12(e) and (f), including those intended to ensure that safe radiation dose levels were used. With one or two exceptions, the requirements of this paragraph were included in the ACR quality assurance manuals that were made part of the interim regulations by reference. The ACR manuals are not referenced in the final regulations. However, certain significant aspects of those manuals, such as the requirements in this section, were incorporated into the proposal because there is broad agreement that these principles are basic to a good quality assurance program.

a. *General comments on quality assurance*

(Comment 439). Two comments stated that all facilities should follow the same set of universal guidelines to maintain the same quality of results.

FDA notes that the MQSA and the implementing regulations are designed to require that facilities meet universal minimum standards. Nothing in the statute or regulations is intended to prevent a facility from applying additional, more stringent standards or procedures that strengthen QC at that facility.

(Comment 440). One comment stated that FDA should eliminate this entire paragraph except for a single provision that would require each facility to have a quality assurance manual and to verify, through the signature of a responsible official, that the manual is followed.

FDA does not believe that the general requirement suggested by the comment would effectively establish minimum levels of quality assurance at all facilities.

b. *Responsible individuals (§ 900.12(d)(1))*

This paragraph identified the responsibilities of the individuals associated with the quality assurance program.

(Comment 441). Two comments recommended that FDA be more specific about what responsibilities should be listed and to whom they should be assigned.

FDA does not believe that additional detail will be useful in these provisions. Greater specificity would limit the facility's flexibility to design a quality assurance program that best meets its individual needs and to quickly change its program in response to changes in circumstances or technology.

(Comment 442). One comment expressed the author's disappointment that this section and the rest of the regulations failed to allot any responsibility to administrators and Chief Executive Officers (CEO's), who have the authority to make the decisions that control quality but seem to be more motivated by financial concerns.

FDA agrees that administrators, CEO's, owners, and operators of facilities share responsibility for the quality of mammography at their facilities. However, individuals working more directly in and with the mammography facility on a daily basis often are better able to determine when quality problems exist and how to correct them. The agency recognizes that it is sometimes difficult for the staff to obtain the administrator's support for necessary actions. Nevertheless, if necessary actions are not taken to correct quality assurance defects, the result could be sanctions against the facility by FDA. Because such sanctions can affect the reputation and profitability of any facility, FDA believes that administrators and CEO's will cooperate to support actions to improve or maintain mammography quality.

c. *Lead interpreting physician (§ 900.12(d)(1)(i))*

This provision requires facilities to identify a lead interpreting physician to have the general responsibility for ensuring that the quality assurance requirements of § 900.12(d) through (f) are met. This is a change from the interim regulations, which assigned this responsibility to a mammography medical physicist. This change drew a number of almost evenly divided comments.

(Comment 443). Eleven comments plus NMQAAC supported the change. Various comments pointed out that the medical physicist often does not have the authority to implement needed actions, especially if he or she is a contract physicist who is rarely at the facility, and the medical physicist usually does not have the expertise to deal with nonequipment issues. One comment noted that Massachusetts' regulations have a similar provision to the proposal and it had been found to improve the quality assurance programs.

Eleven other comments opposed the change. Some of these comments stated the belief that interpreting physicians did not have sufficient knowledge of or interest in quality assurance to properly handle this responsibility. Others said that, in modern medicine, the physicians also lack authority to implement necessary changes and pointed out that interpreting physicians may also be contract employees and not actually at the facility. A related comment warned that, if the interpreting physician is to be given responsibility for oversight, he or she must also have authority to institute necessary changes. One comment stated that while it is important to have an interpreting physician in this role, it is more important to assign this responsibility to someone at the facility, even if it means involving a nonphysician. Another comment questioned the basis for designating a lead interpreting physician if he or she can assign their responsibilities to other people. Two comments suggested that wording be changed to allow each individual facility to decide who would be most appropriate for this responsibility. Finally, one comment stated that the MQSA specifically said that the medical physicist was to have responsibility for the quality assurance program.

After considering all these comments, FDA has decided to leave this responsibility in the hands of an interpreting physician, as proposed. Because the interpreting physician is the final arbiter of the quality of a mammogram, it is logical that the responsibility for the quality assurance program rest with an interpreting physician. The agency recognizes that interpreting physicians in some facilities face the same limitations on their authority as medical physicists. However, FDA believes that an interpreting physician is more likely to have adequate authority, or the ability to influence those that do, than a medical physicist. The agency also recognizes that the interpreting physicians may not be located at the facility itself. Even in those circumstances, interpreting physicians have more regular interaction with the facility through their mammography interpretations than do contract medical physicists conducting annual surveys. Again, the agency realizes that interpreting physicians may not have the knowledge to carry out all aspects of the program themselves, but notes that this is likely to be true of any other individual in this position. For this reason, the final regulations do not require the lead interpreting physician to perform all of the duties personally, but rather to see that they are carried out in such a way as to meet the requirements. The basic responsibility remains with the interpreting physician, even if some or all individual duties are delegated to people with specific training to carry them out. Contrary to the opinion expressed in one comment, identifying a lead interpreting physician is valuable because it assigns this basic responsibility and establishes accountability even when tasks are delegated.

Many important duties will be delegated to the medical physicist. FDA is aware, as one comment noted, of the MQSA provision that requires the medical physicist to ''survey mammography equipment and oversee quality assurance practices at each facility'' (42 U.S.C. 263b(f)(1)(F)). As noted above, the interim regulations did assign to the medical physicist the overall responsibility for quality assurance. FDA's experience under the interim regulations, however, established that the interpreting physician, who ordinarily has more interaction with the facility and is more likely to be onsite, also has an important role in the oversight of quality assurance. As discussed, members of NMQAAC and public comments pointed out problems with the medical physicist having the primary responsibility for all quality assurance at the facility. After evaluating its experience and the comments, the agency proposed, and now intends, to shift overall responsibility for the quality assurance program to the lead interpreting physician. The medical physicist will continue to do the annual survey and oversee quality assurance practices, especially those related to the equipment, as required by the MQSA and the agency expects that the physicist's expertise will inform all final decisions that are made on quality assurance issues. The final regulation, however, requires additional oversight through the lead interpreting physician. FDA believes this change from the interim regulations is in accordance with its general authority to require the facility to establish an effective quality assurance program (42 U.S.C. 263b(f)(1)(A)).

Section 900.12(d)(1)(i) requires the lead interpreting physician to determine whether individuals assigned to quality assurance responsibilities are qualified to carry them out. FDA agrees with the comment that urged that the lead interpreting physician also be given authority to make needed changes because effective quality assurance will require facilities to respond appropriately to situations that need improvement or correction. Internal administrative and budgetary decisions, however, are beyond FDA's authority and the agency cannot control the business and management relationships that will affect any lead interpreting physician's ability to institute change.

d. *Interpreting physicians (§ 900.12(d)(1)(ii))*

This paragraph was intended to emphasize the role that all interpreting physicians should play in establishing and maintaining quality mammography at a facility. As previously mentioned, the interpreting physicians are the final arbiters of the quality of mammography images. It is important that they communicate their satisfaction or dissatisfaction with the quality of the images they are provided to interpret to the technologists who produced them. Such communication is the crucial first step in the identification of problems and the initiation of corrective actions. FDA is aware that this communication has not always occurred in the past, especially if the interpreting physicians are not located at the facility. Media investigations and many anecdotal accounts have illustrated this failure in communication.

None of the 17 comments on this provision disagreed with the basic premise that interpreting physicians should provide feedback to facility staff producing the mammograms. However, there were some misunderstandings as to just what was required.

(Comment 444). In particular, 13 comments mistakingly assumed that each interpreting physician was required to contact every technologist about the quality of each film taken. These comments requested that the requirement be limited to reporting technically inadequate mammograms to the QC technologist. Another comment pronounced the requirement as excellent, but asked whether a report was required on the technologist's performance for every film or if a summary of each technologist's performance was sufficient. Another comment suggested that feedback be given to the lead interpreting physician or, in his or her absence, to the QC technologist. One comment requested that this provision be more specific, and another recommended that all interpreting physicians be required to have training in the technical aspects of mammography, quality assurance, and QC.

FDA drafted the proposed regulation to be general in order to give each facility the flexibility to design a feedback system that best fits its own situation. The agency believes this flexibility should be retained in the final regulations. In response to the comments, however, FDA has clarified that followup activities by interpreting physicians are required only when the image is of poor quality. FDA recommends, however, that positive feedback also be given when warranted because such feedback is an effective incentive for maintaining quality performance.

e. *Medical physicists (§ 900.12(d)(1)(iii))*

This paragraph summarizes the role of the medical physicist in establishing and maintaining quality mammography.

(Comment 445). Eleven of the comments received on this provision suggested various wording changes. Seven of these supported changes that would state that the physicist is to evaluate the equipment and to survey it. An eighth comment wanted to amend the language to give the medical physicist authority to take necessary steps to ensure quality in his or her area of responsibility. Two comments suggested changes that would limit the physicist's responsibilities to overseeing the equipment-related quality assurance practices. These comments further suggested limiting the physicist's review of the QC technologist's work to verifying that it is performed and not to include providing advice on tests or suggestions for corrective measures. Another comment, however, clearly disagreed with this point of view and stated that the medical physicists should be required to oversee the facility's entire quality assurance program.

FDA agrees that the physicist should be involved in equipment evaluation and the annual survey and notes that changes made elsewhere, in the survey definition and in § 900.12(e), will achieve this goal. FDA cannot require that the medical physicist be given authority to initiate changes at the facility to improve quality for the same reasons that it did not issue regulations giving the lead interpreting physician similar administrative and budgeting authority. The agency does agrees that the physicist's oversight responsibility should be focused primarily on the equipment-related areas. The definition of the position of lead interpreting physician in § 900.12(d)(1)(i), as discussed previously, should clarify that general overall responsibility rests with that physician while responsibility for equipment-related matters resides with the physicist. FDA does not agree with the suggestion that would limit the medical physicist's role in the oversight of the QC program to merely verifying that the technologist's work was done. The agency believes that, as the equipment and imaging physics expert, the physicist's role must be more active and that ensuring an adequate QC program clearly should be part of the medical physicist's duties. The medical physicist should not stop with verifying that the QC tests were performed but should also ensure that they were performed properly, that the results were analyzed, and that any problems detected by the analysis were corrected.

(Comment 446). A final comment on this paragraph suggested that a new intermediate position be created at a level between the QC technologist and the physicist. The comment recommended that the person in this position could do tests that do not require a physicist but are beyond a technologist's training, and noted that such a position has been quite useful in the respondent's facility.

Provisions of § 900.12(e) require that surveys and mammography equipment evaluations be performed by medical physicists. Under the interim or final regulations, a facility is free to create an intermediate position for personnel to perform other testing during the time periods between the surveys and evaluations, including performance of the tests normally done during surveys. However, the agency does not have sufficient evidence to demonstrate that it would be beneficial to make this a general requirement and believes each facility is in the best position to decide whether such a position would be of value in its situation.

f. *QC technologist (§ 900.12(d)(1)(iv))*

This provision describes the QC technologist's responsibility to perform all quality assurance duties not assigned to the lead interpreting physician or the mammography medical physicist. The main issue raised by the comments on this provision was about the qualifications of the individual holding this position.

(Comment 447). Eighteen comments expressed the opinion that the person doing these tests should be a radiologic technologist who meets all of the requirements necessary to perform mammography examinations. Seven additional comments stated that the QC technologist should be a technologist but, to increase flexibility for the

facility, should not necessarily have to be qualified to do mammography examinations. One of these seven recommended that the QC technologist should have some training in mammography. Ten comments argued that the individual performing at least some of the tests did not even have to be a technologist, as long as that person had training in the test performance. Some of these pointed out that requiring a technologist to do the tests would increase facility costs without an equivalent increase in the quality of mammography.

After considering the comments, FDA has revised the proposal to permit nontechnologists to perform tasks for which they were trained, as long as their work is supervised by a QC technologist who meets the requirements to do mammography examinations. FDA believes this change strikes the proper balance between the need for expert oversight and the need to reduce unnecessary costs for facilities.

NMQAAC discussed this issue at several meetings and, at different times, expressed varying points of view. However, after its own review of the public comments, NMQAAC supported the approach FDA has taken in the final rule.

(Comment 448). Twelve comments suggested changes, primarily to allow or prohibit the facility from having more than one QC technologist.

FDA agrees that there are advantages to the consistency that can be achieved if there is only one QC technologist. The agency also recognizes that the facility may find it useful and necessary to have more than one QC technologist, e.g., to ensure coverage when one QC technologist is ill or on leave. The agency notes that facilities also have the option of having the lead interpreting physician or medical physicist fill in for the QC technologist, assuming they have the necessary qualifications, by temporarily ''reassigning'' the technologist's duties.

(Comment 449). Another comment suggested that the QC technologist should report directly to the lead interpreting physician rather than to the medical physicist.

FDA notes that the regulations permit the facility to decide for itself what lines of communication to the lead interpreting physician should be established. The agency believes that this flexibility should be retained.

(Comment 450). Another comment suggested that all mammographers should be trained in all QC tests and procedures.

From the context of the comment, it was clear that the author was using the term ''mammographer'' to refer to technologists doing mammography, and not, as is becoming increasingly common, to interpreting physicians interpreting mammography. Section 900.12(a)(2)(ii)(A) does require such training as part of initial training for technologists who will begin performing mammography after the final regulations become effective. Training in these areas could also be used to fulfill initial requirements under the interim regulations, so many technologists presently doing mammography will have had this training. Although FDA encourages all radiologic technologists currently practicing to include such training as part of their continuing education, the agency does not believe that the benefits of retroactively requiring all present technologists to receive this training would outweigh the costs.

(Comment 451). A final comment suggested that adequate time should be allotted for the quality assurance/QC duties.

FDA fully agrees with this comment but does not believe that this kind of commitment can be codified through a regulation. The agency also notes that the amount of time needed will vary significantly, in view of the different situations in different facilities and the differing abilities of the individual QC technologists. As discussed in connection with earlier sections, FDA believes that owners, operators, and managers will have new incentives to ensure that quality assurance programs are properly implemented and that these programs meet the Federal standards with which all facilities must comply.

g. *Quality assurance records (§ 900.12(d)(2))*

The provisions of this paragraph have been significantly changed from the proposal. The proposal required that the facility have a quality assurance manual covering the procedures to be used in meeting the requirements of § 900.12(e) and (f). The manual was to be readily available to all staff members and documentation that it was read and approved by the lead interpreting physician and the medical physicist was required. A list of individuals assigned quality assurance responsibilities and details of their assignments was also to be available to all staff members. Records were to be kept showing that these individuals were qualified for their assigned duties. Records were also to be kept showing the data obtained during monitoring of the facility performance, the analysis of the monitoring data, the problems detected and corrective actions carried out, and the effectiveness of the corrective actions in resolving the problems. The records were to be kept for each test for a minimum of 1 year or until the test had been performed two additional times at the required frequency, whichever was longer.

In response to comments received, as summarized below, and in keeping with the FDA's goal of less prescriptive and more flexible regulations, this paragraph has been greatly simplified. The final regulations do not require any description of the procedures to be followed in performing the QC tests or a list of the individuals with quality assurance responsibilities and their responsibilities. The proposal requiring records documenting the qualifications of these individuals to perform their duties is changed to simply require that records be kept concerning employee qualifications. No review, revision, or sign-off of the manual is required at any frequency but there is a general requirement that the lead interpreting physician, a QC technologist, and a medical physicist are to ensure that records are maintained and updated. The time that the records of testing and followup actions must be kept has been clarified but remains essentially the same.

The proposal divided the provisions of § 900.12(d)(2) into four paragraphs, (i) through (iv). As a result of these changes, paragraphs are no longer needed but the comments received on the proposed four paragraphs will be discussed, following the general comments.

h. *General comments on quality assurance records*

(Comment 452). One comment asserted that keeping quality assurance records was an unnecessary burden but did not suggest an alternative means by which a facility could demonstrate that it had carried out the quality assurance tests and all necessary followup activities. A second comment recommended that mammography facilities be required to retain written specifications in a standardized format from the processor manufacturer.

FDA cannot accept the first of these comments without an adequate alternative to keeping records. FDA agrees there would be value in processor manufacturers providing specifications in a standardized format but believes it would be premature to make this a requirement. The agency's previous attempts to encourage the provision of processor operating characteristics for different types of film showed that there are significant problems to be solved, among them the very large number of

possible combinations of film, chemistry, and processors.

i. *Records to be kept (proposed § 900.12(d)(2)(i), (ii), and (iii))*

(Comment 453). A few comments were received on the records to be kept. Three comments opposed the change from requiring the use of the ACR manual to allowing the use of whatever manual best fits the facility's needs.

FDA believes that the increased flexibility provided by allowing the use of manuals other than the ACR manuals is desirable because it permits facilities to more rapidly adjust their programs to incorporate improvements in quality assurance procedures or new techniques for new technology. When a manual is specified in regulations, the regulations may have to be amended to facilitate use of even a new edition of that manual, let alone an improved manual from another source. To increase flexibility even further, in the final rule FDA has dropped the use of the word ''manual'' altogether because it seemed to imply a certain format. Facilities will now be able to keep the required records in any suitable format.

(Comment 454). A number of comments recommended addition of items to the list of those required to be kept. Six comments suggested adding technique charts to the required records, while a seventh suggested adding documents related to the medical outcomes audit program. Another comment stated that documentation for darkroom cleaning, screens, and view boxes should not be eliminated.

NMQAAC members pointed out that there was already a requirement in the ACR manuals, which were incorporated into the interim regulations by reference, that a technique chart be available. Although there was some difference of opinion, NMQAAC seemed to support retaining a requirement for keeping a technique chart with the equipment but not necessarily in the manual. With respect to the quality assurance manual in general, the view of NMQAAC seemed to be that elements required in the final regulations were ''key'' or ''basic'' to the success of a quality assurance program. At least one NMQAAC member expressed reservations about the detail required and would have preferred to limit the regulation to a general requirement that there be a quality assurance manual. However, both this member and a second member recognized that enforcement by inspectors would be difficult without more detailed requirements.

FDA notes that documentation of facility cleanliness activities is required in § 900.12(e)(11). The list of other records that must be kept, although not necessarily in a ''manual,'' has been revised as discussed previously.

(Comment 455). Other issues that drew a number of comments were who should sign off on the manual and how often should review, revision, and sign-off take place. Nine comments supported having the QC technologist sign-off in addition to the lead interpreting physician and mammography medical physicist. A tenth comment would limit the physicist sign-off to only those items related to his or her responsibility. Three comments stated that the review, revision, and sign-off should occur at least annually. NMQAAC supported both adding the QC technologist to the sign-off list and the annual review, revision, and sign-off.

FDA has replaced the requirement for a formal sign-off with a general statement that the lead interpreting physician, QC technologist, and medical physician should ensure that the specified records are kept.

(Comment 456). Another comment stated that qualifications of the individuals assigned responsibilities in the QC program should be kept on record only if those individuals are not listed in the facility's application (presumably for accreditation).

FDA disagrees with this comment. The accreditation bodies do not check the qualifications of personnel to perform quality assurance tasks during the accreditation process.

Proposed § 900.12(d)(2)(ii), which required that a list be kept of the individuals with quality assurance assignments and their assignments, drew only one comment. The comment supported the list but urged that the requirement be clarified so it was not construed to mean that only the listed individuals could carry out the duties. As discussed above, FDA has eliminated this proposed requirement.

The only comment on the proposal for keeping records of qualifications of quality assurance personnel, § 900.12(d)(2)(iii), suggested that those records should be kept indefinitely. As discussed above, FDA has reworded the requirement slightly. Requirements for record retention are discussed below.

j. *Monitoring performance (proposed § 900.12(d)(2)(iv))*

As proposed, this provision would have required facilities to maintain records related to monitoring of their facility's performance for 1 year or until the tests has been performed two additional times at the required frequency, whichever was longer.

(Comment 457). One comment stated that the words ''for a minimum of 1 year'' should be replaced with ''from inspection-to-inspection'' because inspections may not occur precisely at annual intervals. FDA has changed the wording to ''until the next annual inspection has been completed and FDA has determined the facility is in compliance with the quality assurance requirements.'' This change addresses concerns raised by this comment and clarifies that an inspection includes the followup and the actual visit to the facility.

5. *Quality Assurance—Equipment (§ 900.12(e))*

The primary purpose of the equipment aspects of the quality assurance program is to prevent problems with equipment or detect and correct problems before they can have a significant effect on clinical image quality. In order to achieve this objective, the performance parameters of the equipment must be tested at appropriate frequencies, the test results must be analyzed promptly to determine if the performance of the equipment is satisfactory, and any identified problem must be corrected as soon as possible. Followup tests must also be conducted to determine whether the corrective actions were effective and adequate. Requirements for the types of equipment tests to be performed and for the necessary followup actions were proposed in § 900.12(e). These requirements have generally been retained in the final rule. However, on the basis of a number of valuable comments the agency received in response to its proposals, some revisions to the proposal have been made. Many of the revisions have been made after discussions with NMQAAC. In addition, tests for radiation output and decompression have been added to the annual QC tests as § 900.12(e)(5)(x) and (xi). The action limits for these tests were proposed as equipment specifications in § 900.12(b).

a. *General comments on equipment quality assurance*

In the preamble to the proposal (61 FR 14912), FDA specifically requested comments on the value of a simple daily total system test based upon the evaluation of the optical density and artifacts on an image of a uniform phantom. The agency believed that the total system test, when performed in conjunction with the processor performance test set forth in § 900.12(e)(1), would ensure the overall quality of X-ray machine and processor performance and of the films produced. This test would only takes a few minutes to perform and records of the test would enable a medical physicist to

quickly detect the source of a problem when it occurs.

(Comment 458). A large number of comments opposed the idea of such a test. Several of these comments, however, confused this test with the alternative phantom testing identified earlier as a possible basis for performance-based standards (See 61 FR 14860). Some members of NMQAAC also opposed this test. The agency also received a number of comments supporting this test. Several comments agreed that more frequent phantom testing in conjunction with daily processor testing is important.

In view of the mixed comments, FDA concluded that it should not require the test until it gathers additional data on its usefulness. However, FDA strongly encourages facilities to test their machines as frequently as possible, either by a phantom evaluation or by the total system test.

A number of comments requested that FDA provide a detailed description of all QC test procedures. Several comments wanted FDA to reference ACR QC manual, while some comments considered the proposed Quality Assurance-Equipment requirements to be appropriate.

FDA notes that § 900.12(e)(1) through (e)(5) lists the minimum performance tests to be conducted on screen-film systems and their required frequency. Action limits for the tests are also specified. The agency has refrained from providing extensive detailed requirements or prescriptive descriptions of test procedures, as some comments recommended, in order to provide facilities with the flexibility to use their own judgment as to what testing methods best enable them to meet the required criteria. FDA has also decided not to base its QC requirements on a single manual and, therefore, no such manual has been referenced. In addition, NMQAAC has advised FDA that the ACR manuals were intended to be used as guidelines, not in a prescriptive manner. A facility may consult any appropriate manual on agency guidance to meet the requirements in § 900.12(e)(1) through (e)(5).

(Comment 459). One comment stated that some of the tests should be more rigorous. The comment further questioned why a monthly visual checklist was not included.

While conducting regular visual checks of the equipment is a desirable practice, it is not an action that can be confirmed from test data. Therefore, the agency has decided to encourage this and similar desirable practices through educational means instead of making them regulatory requirements.

(Comment 460). Another comment stated that FDA should only issue more stringent requirements if their benefits clearly exceed their costs.

FDA agrees with this comment and believes that the tests it has required meet this criterion.

(Comment 461). One comment stated that numerous paragraphs refer to films, optical densities, and processors, without limiting the requirements to any specific modality.

FDA notes that the initial words in each paragraph from § 900.12(e)(1) to (e)(5) are ''Facilities with screen-films shall * * *,'' making it clear what modality is referred to.

(Comment 462). Another comment maintained that FDA should require proper QC tests for stereotactic units. One comment stated that the quality assurance standards should include a requirement to use a digital mammography evaluation phantom developed by the author's company that has been designed specifically for QC of digital machines for stereotactic biopsy.

Interventional mammography is presently exempt from the MQSA requirements for reasons discussed in response to the comments on the definition of mammography in § 900.2(y). The agency is in the process of developing quality standards for interventional mammography and these will include QC tests. QC tests for other mammographic modalities have been addressed in § 900.12(e)(6).

(Comment 463). Another comment stated that FDA should provide its inspectors with more latitude to accept variations from regular inspection procedures, if the physicist can adequately explain the rationale for the deviations and demonstrate how the standard is met. From the context, the agency assumes that the author of the comment is actually referring to survey procedures rather than inspection procedures.

FDA has instructed inspectors to discuss variations with QC personnel or medical physicists available in the facility during inspection. In some cases, the inspectors, after receiving satisfactory explanations for variances in test procedures, have refrained from giving citations or withdrawn citations initially given to the facility during inspection. However, because it is essential that the evaluations of facility conformance with the quality standards be consistent nationwide, the latitude provided to inspectors necessarily has to be limited. Moreover, those wishing to use alternatives to the requirements of the regulations who can demonstrate that their alternative provides assurance of quality mammography equal to the regulatory requirement, may do so in accordance with § 900.18.

(Comment 464). A few comments urged FDA to require testing with all cassettes wherever that is appropriate.

In the proposed regulations, the agency proposed that screen speed uniformity of all cassettes in the facility be tested. In the final regulations, FDA added that artifact evaluations should be performed with all cassettes in the facility. The agency also considered requiring performance of the phantom image quality test with all sizes of image receptors. However, when FDA staff members carried out phantom image evaluations using two different image receptor and cassette sizes with five different mammography machines, no difference was seen in the phantom image scores when results with larger image receptors were compared to those with smaller. NMQAAC strongly advided FDA not to require weekly phantom testing for all image receptor sizes because the members do not believe that phantom image quality is affected by receptor size. NMQAAC pointed out that the ACR manual did not recommend phantom image evaluation with large image receptor sizes. Based on all this information, the agency concluded that facilities should not be required to conduct phantom image quality tests with all available sizes of image receptors.

b. *Daily QC tests—screen-film system (§ 900.12(e)(1))*

The only daily tests required under the final regulations are those that ensure adequate processor performance by assessing base plus fog density, mid density, and density difference, using mammography films used clinically at the facility.

(Comment 465). Five comments stated that there should be a maximum limit between time of exposure and time of processing. NMQAAC discussed this issue in connection with requirements for mobile units, for which image degradation due to delayed processing is a particular concern. The committee concluded that, in general, this was not a significant enough problem to require a regulatory requirement and FDA accepted this position.

(Comment 466). Ten comments suggested the word ''examinations'' should be replaced with ''films'' and the word ''performed'' with ''processed.'' The agency agrees with these comments and has made such changes in the final regulations.

One comment suggested adding the words ''and evaluate'' after ''shall perform.''

FDA notes that § 900.12(e)(8) generally defines tests for which the evaluation of test results (and corrective actions) must be performed before further examinations are conducted. The processor tests are among them.

(Comment 467). Several comments suggested that the last few words in § 900.12(e)(8)(ii), ''of no less * * * 1.2 OD, [optical density]'' should be deleted. These comments stated that in some cases, the step averages may turn out to be lower, for example 1.05, and that should be acceptable if the next higher step shows a substantially higher OD, such as 1.4. Another comment offered a similar argument, noting that the proposed rules would not allow the use of modern high gradient mammography films where the change in optical density between adjacent steps in this density range can be as high as 0.7.

FDA agrees with these comments and has deleted ''of no less * * * 1.2 OD'' in § 900.12(e)(8)(ii).

(Comment 468). One comment stated that QC measures should be in place for densitometry and sensitometry equipment.

FDA requires all sensitometers and densitometers its inspectors use to be properly calibrated. If FDA inspectors detect problems in the processor performance, the facility will have to identify the cause. If the cause turns out to be related to inadequate performance of the facility's sensitometry or densitometry equipment, the effort required to determine the nature of the problem will give the facility sufficient incentive to take actions to avoid a recurrence without the need for a regulatory requirement.

(Comment 469). Three comments asserted that the ± 0.15 OD action limits for mid-density and density difference were too restrictive as proposed and requested changing this limit to allow a wider range.

Under the interim regulations, facilities have been required to comply with this limit and the inspection data reveal that most facilities are able to do so. The agency does not find that there is adequate reason for changing this limit in the final regulation.

(Comment 470). One comment stated that a guidance document should be published to provide a clear explanation of the scientific basis for establishing an H&D curve and the importance of parameters taken from this curve to monitor trends in processor QC.

FDA believes that this is a widely accepted practice and the most effective procedure that is currently available. Sufficient materials providing the type of guidance requested already exist.

c. *Weekly QC tests—screen-film system (§ 900.12(e)(2))*

In the proposal, the image quality test using a phantom approved by FDA, which was required monthly by the interim regulations, was made a weekly test.

(Comment 471). Twenty comments opposed changing the phantom testing from monthly to weekly, arguing that the additional cost of performing phantom image evaluation weekly would be burdensome to many facilities. However, a larger number of comments supported this change, many indicating that their facility already performs phantom tests weekly.

FDA is convinced by the experience of the facilities that have been performing phantom image evaluation at a higher frequency that the test should be performed weekly. The agency believes that the benefit outweighs a slight increase in costs. As noted in the preamble to the proposal, if the daily total system test had been required, returning the required frequency of the image quality test to monthly could have been justified. However, because FDA is not mandating the total system test at this time, it is essential that all facilities perform weekly phantom image evaluation as an overall assessment of all aspects of the imaging chain.

(Comment 472). Some comments suggested changing ''image contrast'' to ''density difference'' and ''assess density difference'' to ''assess image contrast'' in § 900.12(e)(2)(iv).

The agency agrees with these comments and has revised the wording.

(Comment 473). One comment stated that the density difference between the background and the test object needs to be defined. The comment further stated that there is presently confusion over the ACR recommendation for a density difference of 0.40 at 28 kVp.

FDA notes that, with the changes made as suggested by the previous comments, it is clear that the density difference is measured between the background and a test object added to the phantom to assess the image contrast. The agency has determined that the regulations should not specify a number for the operating level for this density difference, specify the test objects, or prescribe any technique factors to achieve the desired operating level, because all these variables may change with future changes in technology. However, FDA considers it important that facilities make sure that the measured density does not vary by more than ± 0.05 from the established operating level.

(Comment 474). Several comments considered the requirement of a minimum 1.20 optical density (OD) at the center of a phantom image to be high and believed that many facilities will not be able to meet that standard. One comment stated that higher OD is achieved at the expense of patient dose. Some comments considered 1.20 OD too low. One comment recommended that there be an upper limit of OD. Another comment stated that OD within ± 0.20 is reasonable if the film manufacturer's tolerance is better than 0.3 OD from batch to batch.

FDA believes that proper OD is vital to the early detection of micro calcifications and, with the advent of new mammography screen-film systems, an OD of 1.2 with a variation of no more than 15 percent can be achieved if the processors and the units perform properly. NMQAAC also advised FDA to require that the film OD at the center of the phantom image be no less than 1.2 for the purposes of this test. The agency, however, believes that a requirement for an upper limit on OD may hinder any future development of mammography screen-film systems. Therefore, the agency will retain § 900.12(e)(2)(i) and (ii) as proposed.

(Comment 475). One comment stated that the point of the image quality test is to determine constancy; therefore, it was unnecessary to mandate the measuring position of optical density as the center of the image, as long as the same location is measured each time.

The intention of this requirement is that the OD be measured at the same location of the phantom image each time, as the comment suggested. The agency believes that the center of the phantom image is a reasonable and easy place to locate such measurements. Further, it is not advisable to measure OD too far away from the center towards the anode side of the phantom image in order to avoid a decrease in density due to the heel effect. This could lead to a failure to meet the ≥ 1.2 OD requirement when it might have been met if measured at the center of the same phantom image.

(Comment 476). One comment recommended that § 900.12(e)(2)(iv), the phantom image contrast requirement, be deleted because daily film sensitometry already measures this parameter.

FDA disagrees. The daily sensitometry test only uses light that simulates the screen phosphor luminescence. However, emitted light due to X-ray induced fluorescence from the screen phosphors is different both in spectral dependance and in intensity from the light output from the currently available sensitometry equipment. It is

very important that contrast is evaluated when the film is exposed by the emitted light from the actual screen phosphors, induced by the X-ray beam. For this reason, the daily film sensitometry test cannot replace this test of image contrast.

(Comment 477). Several comments noted that the current phantoms are not tissue equivalent and recommended that FDA specify only one type of phantom and minimum acceptable performance criteria. A related comment urged FDA to provide guidance to establish the adequacy of image quality. Another comment requested specification of the test object and measurement conditions for phantom evaluation.

FDA has refrained from specifying phantom or test object type, performance criteria, or scoring methodology in order not to inhibit future advances in phantom technology. The agency continues to believe that accreditation bodies should establish phantom specifications and related performance criteria. However, as part of its responsibilities for accreditation body approval and oversight, FDA will examine each body's phantom specification and performance requirements, which will have to be substantially the same among the different accreditation bodies.

d. *Quarterly QC tests (§ 900.12(e)(3))*

Two QC tests were required to be performed quarterly in the proposal. These were a test of the fixer retention in film and the repeat analysis.

e. *Fixer retention in film (§ 900.12(e)(3)(i))*

This test determines the quantity of residual fixer in processed film, which is an indicator of insufficient washing. Insufficient washing may have a considerable adverse effect on image quality.

(Comment 478). One comment believed that the fixer retention test should be a semiannual test.

FDA notes that quarterly performance was recommended by the ACR manuals and required under the interim regulations. The agency believes that it is generally accepted that facilities should perform this test quarterly and has retained the frequency requirement of this test as proposed.

f. *Repeat analysis (§ 900.12(e)(3)(ii))*

Facilities must perform this test quarterly with repeated and rejected films. If the repeat or reject rate, calculated as a percentage of the total films included in the analysis, changes by more than 2 percentage points from the rate determined the previous quarter, the cause of the change must be identified. (For example, if the repeat rate the previous quarter was 4 percent and this quarter it is 7 percent, the cause of the change must be identified. If the repeat rate this quarter is 6 percent, no further action is needed.)

(Comment 479). A few comments suggested changing ''repeat'' to ''reject.'' One comment stated that it might be more appropriate to simply refer to repeat rate change, rather than repeat or reject rate change.

FDA believes that while the repeat rate is perhaps the better indicator of unnecessary radiation exposure in the facility, the reject rate gives a better picture of the image quality situation. Both rates give useful information and should be calculated.

(Comment 480). Some comments recommended that FDA define repeat and reject to ensure that all but nonclinical films are analyzed. Several comments requested FDA to clarify that films repeated to correct positioning should be included in the repeat analysis. FDA believes that it is current practice that all repeated films are included in the repeat analysis, regardless of the cause of such repeats, and so a regulation mandating this practice is not needed.

Other comments expressed opinions on the most desirable frequency of the repeat analysis. One comment suggested that all repeats be evaluated and corrective action be taken when possible. Several comments recommended monthly repeat analysis and stated that this test would be less useful if it were done quarterly. Another comment urged monthly repeat analysis with 400 films. Another stated that the current method of repeat analysis every 3 months was sufficient.

FDA believes that low volume facilities would not have sufficient numbers to conduct a meaningful analysis if the required frequency is increased. Similarly, if the minimum number of films is set too high, the time period required to collect them in a low volume facility will be so great that problems could go undetected for a significant period of time. FDA, therefore, has left the required frequency as quarterly and has not specified a minimum number of films to be included in the analysis. The agency notes that nothing in the regulations would preclude a high volume facility from performing the analysis at an increased frequency and with as many films as it wished.

(Comment 481). Several comments urged FDA to include an acceptable limit of repeat rate in the regulations, some suggesting that it be 2 to 5 percent. Two comments wanted FDA to require corrective action to lower the observed repeat rate.

FDA again notes that, while most of these comments referred to ''repeat'' analysis, an analysis of both the repeated and the rejected films is required. In response to these comments, FDA observes that it has long been recognized that the parameter with the greatest impact on the repeat or reject rate is the subjective opinion of the physicians doing the interpreting as to what is acceptable. As noted in the preamble to the proposal (see 61 FR 14860), the repeat or reject rate could be reduced by a facility through acceptance of lower quality films. Any range or maximum value for repeat or reject rate that was established as acceptable through a regulation thus could quickly be rendered meaningless as an indicator of acceptable facility performance by such action. Consequently, the agency believes that, while it is important to keep the repeat or reject rate low, it is more important and useful to assess the cause of any change (increase or decrease) in the repeat or reject rate from the previously determined value. Therefore, the agency has retained the proposed requirement that the cause of a variance of more than 2 percent from the value previously determined must be properly assessed and recorded.

In looking for the cause of the change, the agency strongly advises facilities to assess all the factors that can affect repeat or reject rate. These can include personnel ability and preferences, changes in personnel, or variance in machines, processors, films, or chemistry performance.

(Comment 482). Some comments asked why a decrease of 2 percent requires action.

FDA notes, that while it may appear that a decrease in repeat or reject rate is a desired goal and should not require further assessments of the results, this is not necessarily so. For example, if a facility added a mobile unit to its operations, the interpreting physician might feel a subtle pressure to interpret films taken with that unit that he or she might normally reject because of the greater difficulty in scheduling repeat examinations at mobile units. This practice could lead to a reduction in the repeat or reject rate that does not necessarily indicate an improvement in quality. Therefore, the agency believes that the cause of either an increase or a decrease of more than 2 percent from the value previously calculated must be determined and any corrective actions should be recorded and assessed.

(Comment 483). A few comments stated that repeat analysis for each technologist should be evaluated and followup studies should be standardized. One comment wanted

such analysis performed for each machine used in the facility.

The agency supports the idea that analysis of the repeat rate for each technologist, radiologist, and/or machine can be valuable. However, many facilities with a sufficient volume for a meaningful analysis of their total operation would not have a sufficient volume for meaningful analysis of each technologist, interpreting physician, or machine. For this reason, FDA does not believe that a separate analysis for each technologist, interpreting physician, and machine should be a regulatory requirement. However, the agency recommends that each facility consider whether such analysis would be useful in its particular situation.

(Comment 484). One comment urged FDA to provide more guidance, either in a guidance document or by reference to the ACR QC Manuals, as to criteria for repeat and reject rate evaluation and corrective action. Another comment stated that this section needs to be elaborated to specify the frequency at which this test needs to be performed both for large and small volume facilities, guidelines about whether the analysis should be site- or technologist-specific, and acceptable repeat or reject rates. FDA notes that it has provided guidance for establishing an effective repeat and reject analysis program in the past and may provide additional information in the future. However, the agency believes that, as repeat or retake analysis has been an established procedure in radiology for 20 years or more, abundant guidance is also available from other sources. As stated previously, the agency in the final regulation will not reference any manual in order to provide the QC technologists and the medical physicists with flexibility to design their own analysis, recording, and corrective action procedures.

g. *Semi-annual QC tests (§ 900.12(e)(4))*

The proposal included requirements for semiannual tests of darkroom fog, screen-film contact, and compression.

The test of darkroom fog in § 900.12(e)(4)(i) is intended to be performed to identify light sources in the darkroom that can cause significant mammographic film fogging.

(Comment 485). One comment supported § 900.12(e)(4)(i) as written. The comment further stated that retaining the paragraph as proposed would eliminate variables for inspectors when performing this test. Several comments urged that certain test conditions be required, such as: ''Carry out the test under clinical conditions, with or without the safelight;'' ''use previously sensitized film;'' or ''place the test film on the counter top or on the processor feed tray (if not covered), whichever is closer to a safe light that remains on when the film enters the processor.'' Several other comments recommended adding words such as ''emulsion side up'' or ''where the mammography film is usually handled'' at specified points in the requirement.

After discussions with NMQAAC, FDA concluded that the comments did not provide a basis for amending the provision. The agency has retained § 900.12(e)(4)(i) as proposed, except that the words ''emulsion side up'' have been added for clarification. The agency will provide information on test procedures, as some comments requested, separately. Each facility can design its own procedures to meet the generally accepted features of an adequate darkroom fog test.

(Comment 486). A number of comments suggested requiring the darkroom fog test after any change in the darkroom that could result in an increase in the amount of fog.

FDA agrees that many changes in the darkroom could produce darkroom fog but it also believes that it is difficult to specify which changes will lead to increased film fogging. The agency has left it to the judgment of the facility as to which changes may lead to increased film fogging and thus warrant an additional darkroom fog test.

(Comment 487). One comment recommended that the acceptable value of darkroom fog be raised to 0.10 OD and believed that 60 percent of facilities will not be able to pass the test as written.

FDA does not agree that the majority of facilities will not be able to meet the required acceptable level of dark room fogging within 0.05 OD. This requirement is currently in effect under the interim regulations and the agency's inspection data indicate that most facilities are in compliance with this requirement.

(Comment 488). One comment urged FDA to require a clearly written procedure that ensures that the darkroom tests are performed using mammography films.

The agency considers this a good practice and recommends that facilities adopt such procedures. However, FDA does not believe that this requires a regulation.

The screen-film contact test in § 900.12(e)(4)(ii) is intended to ensure that proper contact is maintained between the screen and film in each cassette used in the facility for mammography.

(Comment 489). Several comments noted that the material of the 40 mesh screen used for the test was not specified and suggested that it be copper or a material with an atomic number similar to copper.

FDA agrees with these comments and has specified the requirement of 40 mesh copper screen in the final regulation. It has also clarified that all cassettes used in the facility for mammography must be tested.

(Comment 490). Two comments asserted that a minimum background density needs to be specified for the screen-film contact test, with one of these stating that it should be 0.60 to 0.85 so that the films are not underexposed leading to false readings. One comment wanted acceptance levels to be prescribed in some detail, while another comment stated that additional information was needed as to what constitutes an adequate screen-film contact test result. Two comments suggested the following criterion: ''Areas greater than 1 cm are not acceptable, five or more areas less than 1 cm are acceptable.''

FDA considers this test very important. A 40 mesh copper screen provides adequate resolution and contrast with a mammography film when exposed to a proper density. However, evaluations of these test results can be subjective and cannot be verified against a quantified acceptance level. Therefore, the agency cannot prescribe a numerical value of acceptance level in the regulation, as some comments suggested, because it would not be readily enforceable. FDA notes, however, that it does not agree with the comment that stated that five or more areas of poor contact with a size smaller than 1 cm are acceptable. The agency intends to provide further information on this test. The agency also notes that advice is also available in most QC manuals.

Compression testing is required to ensure that a mammographic system provides adequate compression and, at the same time that the equipment does not allow dangerous levels of compression to be applied. In the proposal, FDA required the compression device to meet specifications described in § 900.12(b)(12)(i) and, in accordance with § 900.12(e)(4)(iii), to be tested semi-annually to see if the specifications continue to be met. After further consideration, the agency determined that in the final rule it would be more appropriate to treat the compression forces as performance outcomes rather than equipment specifications. As a result, the standards for the amount of the compression force

have been transferred from § 900.12(b) to § 900.12(e)(4)(iii). The comments received on this aspect of proposed § 900.12(b)(12)(i) are discussed at this point with the related comments received on § 900.12(e)(4)(iii).

(Comment 491). A number of comments stated that some of the characteristics of the compression system described in § 900.12(b)(12)(i) did not need semiannual QC testing.

FDA agrees with these comments and, in the final regulation under § 900.12(e)(4)(iii), has required that only the compression force be tested.

Under § 900.12(b)(12)(i)(c) FDA proposed that, 5 years after publication, the compression device shall provide a maximum compression from the power drive between 111 newtons (25 pounds) and 200 newtons (45 pounds).

(Comment 492). Several comments urged FDA to make the compression force requirement in the power drive mode effective immediately, not 5 years from publication as proposed. On the other hand, one comment disagreed with the April 1996, recommendation of NMQAAC that the proposed requirements be implemented 1 year after the publication of the final rules. One manufacturer stated that this requirement would affect approximately 2,000 of their units in the field and noted that it would be impossible to upgrade many of these units to the full 25 pounds. Additionally, the retrofit kit is likely to be very expensive and not welcomed by users who find a precompression force of 17 pounds adequate when accompanied with appropriate manual compression.

Although NMQAAC did recommend making the requirement effective 1 year after publication at its April 1996 meeting, they reversed that position in January 1997 after considering the possible cost of the action. The agency has thus retained in the final rule at § 900.12(e)(4)(iii), the requirement of compression force in power drive mode 5 years from the date of publication, as proposed in § 900.12(b)(12)(i)(c).

FDA, however, also considers it important that all mammography machines used currently provide adequate compression force. Under the interim regulations, facilities are required to use equipment that provides a minimum compression of 111 newtons. The agency is continuing to require this minimum compression force. In case of machines where such force is not available in power drive mode, the facilities may use the manual compression to attain this minimum compression requirement. However, 5 years after the publication of the final rule, all machines must provide a maximum compression force in power drive mode of between 111 newtons (25 pounds) and 200 newtons (45 pounds).

h. *Annual QC tests (§ 900.12(e)(5))*

Section 900.12(e)(5)(i) through (xi) lists a number of tests a facility must perform annually. Action limits for the test results are specified, except for the system artifacts (§ 900.12(e)(5)(ix)) and decompression (§ 900.12(e)(5)(xi)) tests; the nature of these do not allow the agency to provide any quantified acceptance level. The tests described in § 900.12(e)(5)(i) through (ix) were proposed as QC tests. The tests in § 900.12(e)(5)(i)(x) and (xi) have been moved from § 900.12(b) of the proposal after FDA concluded that they are more performance than specification oriented and, therefore, are more appropriately located in § 900.12(e) in the equipment quality assurance section of the final regulation.

(Comment 493). One comment stated that the regulation should require these tests to be done by a qualified medical physicist. FDA notes that this requirement already appears at § 900.12(e)(9), which requires that these tests be done as part of the facility survey and further requires that the survey be performed by a qualified medical physicist.

Two comments questioned why the proposed requirements under § 900.12(e)(5) established testing limits different from those used by the accreditation body. The comments claimed that these ''discrepancies'' will hinder compliance. FDA believes that the authors of these comments are mistaken. The agency assumes that by ''testing limits,'' the comments are referring to action limits. FDA notes that the action limits of § 900.12(e)(5) are the same as those in the ACR manuals, and thus, the same as those the facilities and the accreditation bodies are using under the interim regulations.

The automatic exposure control (AEC) test in § 900.12(e)(5)(i) measures several parameters of the AEC system.

The first action limit specified for the AEC is that it shall be capable of maintaining the film optical density within ± 0.30 of the mean optical density as the phantom thickness and kVp are varied in § 900.12(e)(5)(i)(A).

(Comment 494). Some comments wanted a definition of ''Mean Optical Density.''

FDA notes that such a definition was provided in § 900.2(w) of the proposal, now § 900.2(ee) in the final regulation.

(Comment 495). Other comments asked FDA to specify the type of phantom needed for this test or asked if the same phantom used for the image quality test is required. A related comment stated that the test blocks used by the physicists should be specified to be 15 x 15 mm homogeneous material, in order to ensure an even scatter pattern or distribution that would not be affected by the position of the AEC and inhomogeneous scatter. The comment suggested that phantoms made up of either acrylic or BR12 can be used. Another comment wanted the test details and acceptance levels to be prescribed.

The agency requires the thickness of the phantom to be varied from 2 to 6 cm. These thicknesses are currently required under the interim regulation and the facilities may use any homogeneous material of appropriate thicknesses that will provide a film OD of no less than 1.2 at the center of the image. The agency has previously discussed its rationale for not providing detailed test procedures.

(Comment 496). One comment requested FDA to clarify whether testing is required with all available thicknesses and kVp's. FDA has changed the wording in the final regulation to clarify that AEC tracking is required only for phantom thickness varied over a range of 2 to 6 cm and for kVp's varied appropriately for such thicknesses over the kVp range used clinically.

Proposed § 900.12(e)(5)(i)(C) established an alternative to proposed § 900.12(e)(5)(i)(A) by allowing the development of a technique chart of kVp and density control settings to ensure that the film optical density requirements of § 900.12(e)(5)(i)(A) would be met in cases where it could not be done directly by AEC.

(Comment 497). Two comments stated that a technique chart should be required for all machines under all situations. Two others stated that the proposal created a loophole for the AEC equipment specification requirements proposed in § 900.12(b)(15)(vii)(A). One comment asked if a technique chart would be acceptable in the year 2000 when all machines are expected to meet the ± 0.3 OD variance requirement. One comment suggested eliminating the option of using a technique chart.

The agency has combined the provision permitting the use of a technique chart with § 900.12(e)(5)(i)(A) in the final rule. After consideration of the comments, FDA has decided to permit the use of a technique chart to meet the ± 0.3 OD variance requirement only for 5 years after the publication of the final regulation. After 5 years, the AEC equipment must meet the ± 0.30 OD variance requirement directly.

FDA has moved a provision proposed as an equipment requirement in

§ 900.12(b)(15)(vii)(B) to the quality assurance paragraph as § 900.12(e)(5)(i)(B). As explained earlier, the move was made because this provision was more appropriately located with the QC performance tests than with the equipment specifications. This provision requires, effective 5 years from the publication of this regulation, that the film optical density be maintained within ± 0.15 of the mean optical density at the appropriate kVp-thickness combination. Use of the technique chart to compensate for inadequacies in the AEC will no longer be permitted after that date.

(Comment 498). In response to the original proposal in § 900.12(b)(15)(vii)(B), one comment requested that FDA clarify whether compensation steps using a technique chart will be allowed. The comment also stated that ± 0.15 OD criteria can not be met if the film manufacturers allow 0.3 OD variation from one film batch no another.

As noted in the previous paragraph, FDA will permit the use of a technique chart to compensate for inadequacies in the AEC for 5 years after the publication of the final rule; after that time the technique chart can no longer be used as an aid in maintaining the film optical density within ± 0.15 of the mean optical density at the appropriate kVp-thickness combination. The agency also advises facilities to use films from the same batch so that film variability, if any, is not introduced while testing AEC performance. Because film variability can be eliminated as a source of bias in the AEC performance test, there is no justification for increasing the AEC actions limit to ± 0.30 OD because that would simply mean that the facility would have to contend with variability of ± 0.30 from the film and another ± 0.30 from the AEC.

(Comment 499). Two comments stated that the proposed requirement was too lenient, while two others believed that it was too restrictive. Three comments supported the proposed requirement.

FDA believes, after discussion with NMQAAC, that it is reasonable to require that the ± 0.15 OD limit be met by all units 5 years after publication of the final rule. The agency believes that the cost to meet this requirement will be minimized by the fact that, by the end of this period, many of the units unable to meet the ± 0.15 OD requirement will have been replaced by facilities on their normal replacement schedules. The agency does not believe it has any basis to require a tighter limit than ± 0.15 OD.

Section 900.12(e)(5)(i)(C) (proposed § 900.12(e)(5)(i)(B)) proposed that the operating OD be no less than 1.20.

(Comment 500). Several comments suggested deleting the word ''operating.'' One comment requested the definition of ''Operating OD.''

FDA agrees that the word operating should be deleted. This requirement is now moved to § 900.12(e)(5)(i)(C) in the final rule.

One comment urged FDA to require a mean optical density of at least 1.3 OD. FDA notes that the regulation allows facilities to use a higher film OD if they believe that will make the test a better indicator of the ability to detect micro-calcifications and will aid in improving image quality. However, the agency does not consider it necessary at this time to require any higher OD. The agency also notes that NMQAAC advised FDA to retain the 1.2 OD requirement as proposed.

The annual test in § 900.12(e)(5)(ii) tracks the kilovoltage accuracy and reproducibility.

(Comment 501). A large number of comments stated that kVp accuracy should be within 5 percent instead of the proposed ± 10 percent.

The agency is persuaded by these comments and has made the change in the final regulation.

(Comment 502). One comment questioned the justification of a very tight coefficient of variation for the kVp reproducibility.

FDA believes that the coefficient of variation of a given set of kilovoltage measurements should be less than 0.02, as was proposed. This is the standard presently required under the interim regulations and most facilities are currently in compliance with it; there is no justification for relaxing the standard, either from the point of view of public health or a cost consideration.

(Comment 503). Several public comments and a member of NMQAAC expressed concern that one widely used kVp testing instrument does not read below 23 kV, while kilovoltage settings as low as 21 or 22 kVp are sometime used. A few comments suggested requiring kVp testing at two clinical setting values. One comment stated that § 900.12(e)(5)(ii)(B), as written, could be interpreted to mean kVp reproducibility should be measured from 25 to 30 kVp in 0.5 kVp increments. Another comment stated that it should be acceptable to test kVp reproducibility in just one setting within the clinical range.

In response to these comments, FDA has revised the final regulation to require that the lowest kVp at which accuracy be tested is the lowest clinical used kVp that can be measured by a kVp test device. The agency, however, disagrees with the comments that recommend testing kVp at one or two clinical settings only. FDA considers it important to test kVp accuracy at least at the highest and lowest measurable clinically used values, and at the facility's most commonly used clinical kVp. The agency, however, has modified the regulation to require that the coefficient of variation of reproducibility be determined at the most commonly used kVp only.

One comment claimed that the kVp accuracy requirement should be checked with all focal spots. The agency has no reason to believe this is necessary.

The focal spot condition (proposed as system resolution) test in § 900.12(e)(5)(iii) was proposed to evaluate the performance of the mammography unit by assessing the resolution capability of the system.

(Comment 504–505). A few comments stated that some mammography machines could not meet the proposed resolution requirement even though the focal spot size was adequate. One comment maintained that the line pair resolution requirement was too restrictive. A member of NMQAAC stated that, in magnification mammography, the resolution requirement would be difficult to meet. These comments suggested that the focal spot size measurement be added as an alternative requirement, as is the current practice under the interim regulation. Two other comments also urged FDA to continue to permit focal spot dimension measurements as part of acceptance tests for mammography equipment evaluation. One comment supported replacing focal spot measurement with performance related specifications of system resolution.

FDA considered the immediate economic impact on facilities of meeting the resolution requirement as proposed and decided to permit continued use of the focal spot size measurement as an alternative to the measurement of system resolution for a period of 5 years from the publication of the final regulation. During this period, facilities may evaluate the condition of the mammography unit by determining either the system resolution, proposed as § 900.12(e)(5)(iii) (new § 900.12(e)(iii)(5)(A)), or the focal spot dimensions as described in § 900.12(e)(5)(iii)(B). The agency believes that by the end of this period, when the regulation will require the evaluation of system resolution only, many of the units unable to pass the system resolution test will have been replaced by the facility on its normal replacement schedule.

The agency believes the benefits of assessing overall performance of the system through use of the system resolution test justify their transition. NMQAAC also advised FDA to require the system resolution test.

(Comment 506). One comment suggested that FDA should only require that the resolution shall be sufficient so that the system can detect micro-calcifications of 300 µm and greater sizes.

FDA notes that available scientific data indicate that 50 µm resolution is necessary in mammography imaging for early and proper detection of micro-calcifications. This is equivalent to about 10 cycles (lp)/mm resolution when the bar pattern is used. The agency believes that all new equipment meets this requirement as proposed. Under the interim regulation, this criterion is already being met by the facilities which chose to evaluate focal spots by assessing system resolution. Further, NMQAAC advised FDA to adopt such a requirement in the final regulation. For these reasons, the agency did not accept the comment.

(Comment 507). A member of NMQAAC advised FDA that the units should be specified in SI units and suggested using ''ycles/mm'' in place of ''ine pairs/mm.'' One comment stated that the height of the line-pair test pattern above the image receptor must be specified in association with the resolution limits and suggested that the height should be 4.5 cm. Other comments requested clarification of ''parallel'' and ''perpendicular'' to the axis in terms of the bars of a test pattern whose orientation was being described. Three comments urged that test specifications be included in the regulations.

In response to these comments, FDA has added a new § 900.12(e)(5)(iii)(A) to specify that the high contrast resolution bar patterns must be placed 4.5 cm above the breast support surface and be oriented parallel and perpendicular to the anode-cathode axis. FDA has also introduced cycles/mm as the primary unit.

(Comment 508). One comment asked at what magnification the system is required to resolve 11 and 13 lp/mm. Another comment suggested that the tests should be performed at all magnifications used. Two comments urged FDA to require focal spot assessment for all focal spot sizes. One comment suggested that the system resolution should be tested with the grid in use. One comment suggested that the grid should not be in the imaging chain during magnification.

FDA reiterates that 5 years from the date of publication of the final rule, all facilities must perform the system resolution test annually and must meet the requirements specified in § 900.12(e)(5)(iii)(A)(1), both in contact mode and in all magnification mammography modes used in the facility. The agency believes that if a machine can meet the requirements using the large focal spot size used in contact mode, it will meet the requirements using the small focal spot size also. The agency also believes that the resolution test must be conducted under the normal operating condition, that is, for contact mammography the resolution assessment must be performed with the grid in place whereas for magnification mammography, the grids should be removed. The agency intends to provide more discussion about these procedures in educational documents.

(Comment 509). Two comments stated that the line-pair minimum should be increased.

FDA believes that the present values are generally accepted as representing the best cost/benefit compromise.

(Comment 510). One comment recommended requiring a monthly phantom test with indicators of what should be expected in resolution capabilities at a given magnification to ensure adequate performance between physicist surveys. The comment also recommended that the system resolution in magnification mode be monitored to determine whether it diminishes with time.

Although it encourages facilities to carry out this type of performance-based study, FDA does not believe there is adequate evidence to show that these additional tests would produce benefits that outweigh the costs facilities would incur in performing them. Therefore, at this time, the agency is not including them in the regulation.

The beam quality and half-value layer (HVL) paragraph as proposed in § 900.12(e)(5)(iv), required the HVL to meet the specifications provided in § 900.12(b)(11). Two comments stated that the exact specifications should be included under § 900.12(e)(5)(iv), rather than merely by reference. Two comments suggested that the upper HVL limits described in the 1994 ACR QC Manual should also be included and that HVL limits should be specified for other target filter combinations.

In the final rule, FDA has specified HVL requirements only in § 900.12(e)(5)(iv). The specifications for kVp's in the mammographic range are provided in a tabulated form. Values not shown in the table may be determined by linear interpolation or extrapolation. NMQAAC members were unable to reach a consensus on the value of having an upper limit of HVL or on what the upper limit should be. FDA views this as an indication that there is a general lack of consensus on this topic in the mammography community and, therefore, the agency has decided not to include any upper limit in the regulation.

The breast entrance exposure and AEC reproducibility paragraph, as proposed in § 900.12(e)(5)(v), established the action limit for the coefficient of variation of these two variables at 0.05.

(Comment 511). Three comments suggested deleting the breast entrance exposure requirement, while another considered it to be an equipment standard. This last comment further stated that lack of AEC reproducibility will be identified by other QC tests and the phantom image. Another comment inquired whether it was the intent of the provision to require facilities to calculate exposure reproducibility for data points consisting of mR divided by mAs, or to separately measure the reproducibility of exposure and mAs.

FDA believes that this test must be performed at least annually and that the coefficient of variation must be calculated for both exposure and mAs. If a unit does not indicate a post-exposure mAs value, then mAs should be obtained by a secondary method. In accordance with the movement towards the use of SI units discussed in connection with the new definition of air kerma (§ 900.2(d)), the agency has also introduced air kerma as the primary quantity to be measured in this test. Breast entrance exposure remains as an alternative quantity.

The dosimetry test in § 900.12(e)(5)(vi) determines the mean glandular dose delivered during a single cranio-caudal view using an FDA approved phantom simulating a standard breast. When the mean glandular dose exceeds 3.0 mGy, corrective action is required.

(Comment 512). A number of comments were received on the specifications for the phantom to be used in performing this test. Some comments stated that most facilities are using phantoms simulating a 4.5 cm breast and it would not be cost effective to change to phantoms simulating a 4.2 cm breast. One comment suggested that FDA should recognize that most technique charts are set using whole number thicknesses, arguing that 4.0 cm is probably the most reasonable. One comment stated that ACR phantoms are not tissue equivalent phantoms.

Another comment stated that, to date, most dose data had been set using the RMI accreditation phantom. The comment questioned its actual tissue equivalence and further stated that dose standards should be set using a phantom that correlates as closely as possible to actual thickness.

In the preamble to the proposal (61 FR 14912), FDA solicited comments about actual thickness that the existing phantoms simulate. FDA did not receive enough evidence in response to this question to convince the agency that the existing phantoms simulate a 4.0 cm compressed breast more closely than they simulate a 4.2 cm compressed breast, which is the figure currently used. The agency, therefore, continues to require that the dose should be determined under the assumption that the phantom simulates a 4.2 cm compressed breast and that the technique factors should be chosen accordingly. FDA did not propose, nor has it required in the final rules, any change in the phantoms currently being used. As stated earlier, the agency believes that accreditation bodies should establish phantom specifications and related performance criteria. In the future, if better tissue equivalent phantoms are available to simulate a different compressed breast thickness that can change dose calculations significantly, the agency will revise the thickness requirement for average dose calculation. FDA also notes that a change from 4.2 cm to 4.0 in thickness does not result in a significant change in the calculated dose.

(Comment 513). One comment stated that calculation of the entrance dose to the phantom is not necessary if kVp, HVL, and mAs for the exposure are within limits. Another comment stated that, because the existing image quality phantom simulates a 4.2 cm compressed breast, not 4.5 cm, the dose limit could be lowered. One comment stated that the regulations should not allow any dose less than 0.8 mGy, while another comment stated that there is no reason for accepting 300 mrad as a maximum mean glandular dose because, even at 25 kVp, the typical mean glandular dose is 120–150 mrad (1.2–1.5 mGy). This comment recommended setting the dose limit at 250 mrad (2.5 mGy). Another comment recommended that FDA consider lowering the patient dose requirements to that of the State of California requirement.

FDA strongly believes that a proper dose calculation at least once a year for each unit is critical for public health and safety. FDA further believes that the present dose limit of 3.0 mGy provides adequate protection from unnecessary radiation and does not want to change the dose limit to 2.5 mGy or establish a lower limit of 0.8 mGy, in order to avoid the possibility of inhibiting future advances in imaging technology, as discussed in the preamble to the proposal (61 FR 14912).

(Comment 514). One comment suggested that the phantom kVp and mAs must be compared to the average of 20 or more 4.2 cm clinical breast mammograms to ensure that the measured glandular dose is consistent with patient radiation doses.

In response to this comment, the agency notes that the dose must be determined with technique factors and conditions used clinically for a standard breast. The agency understands that, for some facilities, commonly used technique factors may be slightly different from what would be technique factors for a standard size breast and therefore different from what would be used for the available phantom, which simulates a standard breast. However, the agency does not believe that dose will vary so significantly that it will exceed the required limit of 0.3 mGy in cases of patients with non standard breast size, as long as the mammography unit is capable of meeting the dose requirement using a phantom simulating a standard breast.

(Comment 515). Two comments urged FDA to require that the time of exposure be less than or equal to 2.5 seconds. FDA did not accept this comment because the agency believes that it does not have enough evidence to confirm that 2.5 seconds is the absolute maximum exposure time needed to cover all patient sizes. The agency recommends that facilities determine the proper exposure time for their needs through consultation with the medical physicists and the equipment manufacturers.

The requirements for X-ray field/light field/image receptor/compression paddle alignment in § 900.12(e)(5)(vii) are intended to ensure that: (1) All systems have beam limitation devices that prevent the patients from receiving unnecessary radiation dose, permit imaging of the critical breast tissue near the chest wall, and avoid white borders on the film; (2) if a light field is provided, the congruence of the light field with the X-ray field should be such that the sum of misalignments on opposite sides between X-ray field and light field is within 2 percent of the SID; and (3) the alignment of the edge of the compression paddle with the chest wall edge of the image receptor is sufficient to permit pulling the breast tissue away from the chest wall for imaging and to keep the shadow of the vertical edge of the paddle from being visible on the image. The test also ensures that the extension of the edge of the paddle is within 1 percent of the SID so that the patient's chest is not pushed away from the breast support surface.

(Comment 516). One comment stated that § 900.12(e)(5)(vii) should include exact specifications rather than just a reference to those specifications in § 900.12(b)(5). One comment argued that confinement of the X-ray field within the image receptor cuts off useful film area and misses some of the breast tissue. The comment further suggested that this requirement should be changed so that the X-ray field can extend slightly beyond the edges of the image receptor in order to make full use of the film area and not potentially miss any breast tissue that is overlying the image receptor, and to blacken what would be an otherwise clear border.

In the final regulation, FDA has moved the X-ray field/light field/image receptor/compression paddle alignment specifications to § 900.12(e)(5)(vii). FDA notes that § 1020.31(f)(3), which the agency referenced in the proposal, allows extension beyond the chest wall edge of the image receptor by as much as 2 percent of the SID so as to properly image breast tissue on the chest wall side. In the final rule, the agency allows extension of the X-ray field beyond all edges of the image receptor but limits this extension to within 2 percent of the SID.

(Comment 517). Two comments suggested that the term ''image receptor'' should be defined. In the agency's earlier discussion of the definitions, the agency has referenced § 1020.31 as providing a definition of image receptor.

(Comment 518). One comment stated that the requirement for a light field in this section imposes an unwarranted expense.

FDA notes that a light field is not required but if one is present, it must meet the light field-X-ray field alignment requirement.

(Comment 519). One comment urged FDA to consider relaxing the requirement for the alignment of the compression paddle and the breast support surface. One comment questioned whether limiting the extension of the compression paddle beyond the image receptor to within 1 percent of SID is achievable in all units. Another comment suggested that this requirement be written to more accurately reflect the need to extend past the edge of the image receptor, although by no more than 1 percent of the SID. Three comments stated that it appeared from the proposed regulation

that it was permissible for the compression paddle to be visualized on the mammography film.

FDA believes that the one percent extension limitation can be achieved and notes that the current requirement under the interim regulations is one percent. The agency has also clarified the final rule to emphasize that the shadow of the compression paddle shall not be visible on the image.

(Comment 520). One comment requested clarification on whether the reference was intended to be with respect to a vertical line or with respect to a line connecting the focal spot and edge of the image receptor when the requirement that the chest wall edge of the compression paddle not extend beyond the chest wall edge of the image receptor by more than one percent of SID is being met.

(Comment 521). One comment suggested that FDA specify whether this requirement is with respect to the interior surface of the paddle or the exterior surface. The comment, however, acknowledged that this is not an important issue with a 1 or 2 mm paddle thickness.

FDA disagrees with comments that suggest including all these details in the regulation. However, the agency wishes to clarify that the reference is the vertical line and the requirement refers to the interior surface of the paddle.

One comment stated that this requirement should be met with all image receptors. FDA notes that the regulation as written requires this test to be performed for all full-field aperture sizes used for beam limitation in the facility; this will ensure that all image receptors meet the requirement.

The screen speed uniformity test, as proposed in § 900.12(e)(5)(viii), requires that at least once a year, each facility must ensure the consistency of the screen speed among all cassettes used in the facility for mammography. The same test is required currently at the same frequency under the interim regulation.

(Comment 522). One comment stated that § 900.12(e)(5)(viii) did not allow for slow and fast screen variations due to large and small screens having different relative speeds. Another comment suggested that the maximum optical density difference should be reduced to 0.15.

FDA believes that the difference between the screen speeds of all cassettes, small or large, should be such that the OD variation is within 0.3 OD. The agency, however, does not believe that tightening the restriction on density difference to 0.15 is justified. Members of NMQAAC supported this view.

One comment requested FDA to describe the test procedure to be used. As discussed earlier, FDA made a general decision to refrain from describing specific test procedures for QC tests in the regulations. The agency will include a more detailed description of some tests in its guidance document.

System artifacts in § 900.12(e)(5)(ix) mean artifacts produced by any part of the mammographic system, including the X-ray machine, screen-film system, and/or processors. This subparagraph requires the facility to determine the level and possible adverse effects of artifacts produced by its systems. These artifacts should be distinguished from the patient related artifacts.

(Comment 523). One comment stated that the evaluation should be done for all full-field image receptor sizes.

FDA agrees and has added this requirement to the final regulation.

(Comment 524). One comment recommended elimination of this test because the physicists always watch for artifacts whenever a film is taken.

FDA strongly believes that a separate test solely meant for artifact evaluation is necessary. Further, this test should also evaluate the whole imaging chain for the source of any artifacts detected.

(Comment 525). One comment stated that the test can also be done with a smaller phantom positioned closer to the collimator. As advised by NMQAAC, FDA proposed that artifacts should be evaluated through the use of a test object of high grade defect-free material that is large enough to cover the mammography cassette.

FDA notes the intent in requiring an object of this size is to capture and identify artifacts that are caused anywhere in the cassette and its screen-film combination. In this way, the quality of the entire film can be better assured. FDA understands that there may be other ways of accomplishing this goal, such as the method suggested in the comment, but the agency lacks data to confirm that the suggested procedure will produce equivalent results. The agency notes that the alternative requirement mechanism of § 900.18 provides a way by which alternatives to the requirements can be evaluated, and possibly accepted, by FDA.

(Comment 526). One comment stated that more guidance should be provided on evaluating artifacts. One comment wanted the test details and acceptance levels prescribed.

Again, FDA has decided that test details are subjects more appropriately addressed separately from the regulations. The agency also notes that the acceptance level for artifacts is at present a subjective assessment and not amenable to the establishment of specific numerical standards.

(Comment 527). One respondent believed that testing X-ray systems for artifacts does not require the use of a test object. Another comment stated that use of a thick (4 cm) acrylic test object will harden the beam to the point that it will mask grid and/or carbon fiber cover artifacts and may even mask grid lines.

FDA disagrees. The agency believes that an exposure time sufficient to image appreciable artifacts may not be achieved if a test object is not used, while these artifacts would be visible during a normal patient exposure.

FDA has moved the radiation output requirement from § 900.12(b)(15) to § 900.12(e)(5)(x) because it concluded that it was more appropriate to treat this test as an annual QC test rather than an equipment specification. This test is intended to determine if the mammographic system is capable of producing a minimum required output. Five years from the publication of the final rule, the requirement will change to require a higher output from each system.

(Comment 528). Two members of NMQAAC opposed this requirement as an annual test. One member stated that a 3-second field test of the unit may cause damage to the tube. The same NMQAAC member further stated that averaging the results over a 3-second exposure time would not reveal whether the output rate dropped unacceptably low at any time during the exposure.

FDA does not have evidence indicating that any significant fluctuation in exposure takes place within an exposure time of the order of 3 seconds. However, the agency has revised this requirement in § 900.12(e)(5)(x)(B) from that originally proposed in § 900.12(b)(14) to clarify that no instantaneous radiation output requirement is intended; instead, the requirement is the output averaged over a 3-second period. Also, because the exposure times can be lengthy for some patients, the agency does not consider 3-second exposure time unreasonable. The agency also considers a yearly check of radiation output important and reasonable.

i. *QC tests—other modalities (§ 900.12(e)(6))*

This provision requires facilities using image receptor modalities other than screen-film to establish a quality assurance program that is substantially the same as that recommended by the image receptor manufacturer, except that the maximum allowable dose is not allowed to exceed that established in

§ 900.12(e)(5)(vi) for screen-film systems.

No public comments were received on this paragraph and it has been codified as proposed.

j. *Mobile units (§ 900.12(e)(7))*

This provision requires mammography units used at more than one location to meet all of the quality assurance requirements established in § 900.12(e)(1) through (e)(5). In addition, at each visit at each examination location, before any additional examinations are conducted, the facility is required to verify the performance of such units using an adequate test method.

(Comment 529). Three comments supported the additional testing of mobile units. One of these noted that the many environments in which the units operate made the testing necessary. Six comments opposed the additional testing. The most common reasons given for the opposition was concern about being able to process the test images before mammography is performed and that the additional testing was unnecessary because moving the unit did not create any problems.

When the need for additional testing of mobile units was discussed at the NMQAAC meeting of September 1994, it was noted that a recent ACR survey of facilities operating mobile units had found that about one in seven facilities reported quality problems with their mobile units at least weekly. Largely based on this information, NMQAAC recommended that postmove, preexamination testing of mobile units be included in the final regulations. NMQAAC continued to support this proposed requirement at its January 1997 meeting.

FDA agrees that no change should be made to the proposal. The agency further notes that several of the opposing comments based their concern upon the difficulty of processing phantom images at the mobile site. However, the final regulation does not require the use of any specific test, only that the test method be able to verify that adequate image quality is being produced by the unit. This gives the facility the option of using other tests that do not require processing of images before examinations are conducted, as long as the test can demonstrate that adequate image quality is likely to be achieved. One such test, based on the consistency of mAs readings, was described by a speaker at the September 1994 NMQAAC meeting.

(Comment 530). Five comments expressed concern about the fact that acceptable testing methods were not specified in the regulations. Three of these comments asked who a facility should consult to determine if its test method would be considered adequate by FDA. Related comments on this issue asked how inspectors would determine adequacy without guidance and noted that the State of Massachusetts left it to the medical physicist to determine what test method should be used. One comment urged that a test based on the mAs reading be considered acceptable, while another stated the performance test required by the State of Illinois should be recognized by FDA.

FDA plans to issue information describing test methods that it is likely to consider acceptable for verification of performance of mobile units after a move and before examinations are conducted. It is expected that at least one of these methods will not require the processing of images before the examinations begin. Because these methods will not be regulatory requirements, FDA may accept other test methods proposed by facilities, medical physicists, or other interested parties. Facilities are always free to discuss any particular method with FDA prior to establishing its use.

(Comment 531). One comment opposed allowing central film processing for mobile services out of concern for degradation of the latent image during the time between exposure and development.

This issue was discussed at some length at two NMQAAC meetings and the conclusion was that this degradation would not be significant during the typical times between exposure and development of mobile facility images. FDA, therefore, has not prohibited central processing.

(Comment 532). One comment stated that if diagnostic imaging is done at a mobile facility, a radiologist should be present. Practice of medicine issues have made it difficult to define the distinction between screening and diagnostic mammography. Because of this difficulty, FDA has issued the final regulations to apply to all mammography, rather than addressing specific requirements to one area or the other.

k. *Use of test results (§ 900.12(e)(8))*

The provisions of this proposed paragraph were intended to ensure that the facility did not stop with the performance of the quality assurance tests but analyzed the results of the tests to determine if problems existed and took necessary actions to correct those problems. Ongoing anecdotal evidence and the MQSA inspection data indicate that, even 20 years after the introduction of the concepts of quality assurance, some facilities are still neglecting to take the important final steps in the process.

Section 900.12(e)(8)(i), as proposed, requires facilities to compare the results of their quality assurance tests with action limits specified in § 900.12(e)(1) through (e)(6) and, if their results fall outside the action limits, to repeat the tests immediately to verify that the testing process was not responsible for the result.

(Comment 533). Thirteen comments opposed, at least in part, the requirement to repeat the tests immediately. Some of these comments urged that it be applied only to the processor QC, screen-film contact, and average glandular dose tests. Two comments supported exempting annual tests. Four of the comments stated that the decision about what tests should be repeated should be left to the medical physicist. NMQAAC recommended complete deletion of the proposed requirement that the tests be repeated immediately. One comment took the opposite view, stating that this requirement helps facilities identify trends.

FDA notes that this requirement was originally added to ensure that the facility confirmed whether the problem was due to the equipment rather than an improperly performed test before it went to the trouble and expense of taking corrective actions. However, the agency has been persuaded that a facility that goes to unnecessary expense to correct an equipment problem that was actually a testing problem is likely to take steps on its own to avoid repetition of such a situation. In view of that conclusion, and the public comments, the requirement to repeat the test has been deleted from the final regulations.

Section 900.12(e)(8)(ii), as proposed, stated that if the repeated tests continue to produce unacceptable results, the problem shall be identified and corrected before any further examinations are performed.

(Comment 534). Seven comments stated that this provision, as proposed, was too broad and that at least in some cases it would not be necessary to shut down the entire facility until the problem was solved. Other comments gave the views of their authors as to which tests, if failed, indicated problems serious enough to require the facility to stop doing mammography until the problem was solved. The most frequently mentioned tests in this category were the processor QC tests of § 900.12(e)(1) and the average glandular dose test of § 900.12(e)(5)(vi), each of which was listed by 13 comments.

(Comment 535). Seven comments included the image quality test of § 900.12(e)(2) and six each, the screen-film contact test of § 900.12(e)(4)(ii), the compression test of § 900.12(e)(4)(iii), the tests for modalities that did not use screen-film of § 900.12(e)(6), and the additional test for mobile units of § 900.12(7) on their lists of tests important enough that their failure required problem detection and correction before mammography continued. The system resolution test of § 900.12(e)(5)(iii) was listed in five comments. One comment each also would include the artifact test of § 900.12(e)(5)(ix) (if there were ''serious'' artifacts), the kVp test of § 900.12(e)(5)(ii), and tests of output and the phototimer (if the errors were ''large'') on the list.

NMQAAC as a group supported the requirement that the problem must be corrected before mammography continues only in the cases of the processor QC tests, the average glandular dose test, and the screen-film contact test. However, the medical physicists serving as committee members and consultants for NMQAAC, when discussing specific tests in their individual comments, presented somewhat different and conflicting views. They agreed that the processor QC and the average glandular dose tests were of sufficient importance that, if they were failed, the facility should cease doing mammography until the problem was corrected. They also supported adding the image quality test to that list. Opinions of these physicists were split on whether the screen-film contact test, the automatic exposure control tests of § 900.12(e)(5)(i), the breast entrance exposure and AEC reproducibility test of § 900.12(e)(5)(v), the tests for modalities other than screen-film, and the additional test for mobile units should be considered important enough that their failure would require problem correction before mammography continued.

After consideration of the comments, FDA agrees that not all test failures are serious enough to require the facility to cease doing mammography until the source of the problem is corrected. The agency also agrees with two additional comments that stated that, even if the test failure does indicate a problem that requires immediate correction, it may not be necessary to shut down the entire facility. For example, if the processor QC tests are failed, it may be possible to continue to perform mammography, but to delay processing the films until the processor problem is corrected, as long as the anticipated processing delay is not of such duration that image degradation becomes a concern. Similarly, if the facility has more than one mammography unit, the failure of one unit would not be a reason for stopping the use of another unit that did pass the tests.

In response to these considerations, FDA has revised § 900.12(e)(8)(ii) by dividing the tests into two groups. Those tests listed in § 900.12(e)(8)(ii)(A) are those whose failure requires immediate problem evaluation and correction. However, the wording has been changed to state that the corrective actions must be taken ''before any further examinations are performed or any films are processed using the component of the mammography system that failed the test'' (emphasis added). If the failure is related to a component for which there is no alternative, for example, a failure of the facility's only mammography unit, then the facility will still have to cease doing mammography until the problem is corrected. However, if there is another unit or processor that has passed the tests, the facility will be able to continue producing and processing mammograms with that equipment while the problem with the first unit is corrected.

Included in § 900.12(e)(8)(ii)(A) are the processor QC tests (§ 900.12(e)(1)) and the average glandular dose test (§ 900.12(e)(5)(vi), both of which everyone who commented on this paragraph agreed were important enough that their failure required evaluation and correction of the problem before the piece of equipment was used for further mammography. FDA has also included the image quality test (§ 900.12(e)(2)) in this group, even though it was mentioned in fewer comments. The importance of this test is underscored by the fact that the primary goal of the MQSA is to ensure adequate quality mammography for all women. The agency has also included the additional test for mobile units (§ 900.12(e)(7)) because it is a test that directly evaluates image quality.

FDA has also included the tests for nonscreen-film modalities (§ 900.12(e)(6)) on this list. This particular provision was intended to facilitate the introduction of new modalities because it ensures that facilities using the new modality will have an adequate quality assurance program, while at the same time not requiring amendment of the requirements of § 900.12(e) before the new modality can be used. Because it is not possible to predict in advance what new modalities may appear and what QC tests may be required for them, FDA believes they must be placed in § 900.12(e)(8)(ii)(A) to adequately protect the public. Should it prove to be the case that some or all of the tests that are applicable to the new modality might more appropriately be placed in § 900.12(e)(8)(ii)(B), regulatory relief can be provided through the alternative requirements mechanism of § 900.18 until § 900.12(e)(8)(ii) can be amended.

FDA has also agreed with comments urging that the screen-film contact test (§ 900.12(e)(4)(ii)) and the compression test (§ 900.12(e)(4)(iii)) be placed on the list of those tests whose failure should require taking a piece of equipment out of service until the problem is detected and corrected. The agency notes that the new wording referred to above means that failure of the first of these tests only requires taking the cassette in question out of service and, as one comment pointed out, the corrective action most likely will simply be replacement of the cassette. The compression test is included out of concerns raised by both anecdotal accounts and reports to FDA's Medical Device Reporting System of injuries resulting from excessive compression and the knowledge that inadequate compression can lead to poor quality images.

Finally, FDA retained the darkroom fog test (§ 900.12(e)(4)(i)) on this list, even though it was not mentioned by any of the comments. FDA has concluded from studies, such as the Nationwide Evaluation of X-ray Trends program of the Conference of Radiation Control Program Directors, that excessive darkroom fog is more pervasive and has a greater impact on image quality than is commonly realized. The agency also notes that the detection and correction of the problems contributing to darkroom fog is a relatively uncomplicated process and can be carried out relatively rapidly. Often the problem is associated with the safelight and simply discontinuing use of the safelight until it can be replaced or repaired may provide a temporary correction that would permit returning the darkroom to service.

FDA has placed all other tests under § 900.12(e)(8)(ii)(B). These are tests whose failure indicates that there are problems that must be corrected, but, for various reasons are not considered to present a health hazard serious enough to require taking a piece of equipment out of use until the problem is corrected. Retake analysis is included in this group (§ 900.12(e)(3)(ii)). In this case, mammography must be allowed to continue to determine if the corrective action has indeed had the desired effect on retake rate. Also in this group are tests such as kVp accuracy (§ 900.12(e)(5)(ii)) and alignment (§ 900.12(e)(5)(vii)), for which, as one of

the NMQAAC physicists argued, there are compensation methods that can be used as temporary corrective actions until the problem can be given a more permanent correction. Other tests included in this group, such as the system resolution test (§ 900.12(e)(5)(iii)—called the focal spot condition test in the final regulations) are early warning tests that give an indication of possible approaching problems. In the case of the system resolution test, FDA has accepted the argument of the NMQAAC physicist who believed that, unless the system resolution was so poor as to lead to failure also of the image quality test, some time could be permitted for the correction of the resolution problem. Of course, if the image quality test is failed, the piece of equipment will be taken out of service until the problem is corrected. Finally, this group includes the artifact test (§ 900.12(e)(xi)), for which there are no objective action limits against which to compare the test results.

Although problems revealed by the tests in the second group are not considered serious enough to take a piece of equipment out of service until corrected, FDA believes that they must not be allowed to exist indefinitely. Therefore, § 900.12(e)(8)(ii)(B) requires that when tests in this group are failed, the problems must be evaluated and corrected within 30 days.

l. *Surveys (§ 900.12(e)(9))*

This paragraph required that a facility survey be performed by a medical physicist no less often than once a year. The tests and reviews that, at a minimum, were to be included in the survey were specified along with requirements that the medical physicist provide a survey report to the facility within 30 days of the survey. Identification of those who performed the survey was to be provided in the report.

(Comment 536). Two comments were received on § 900.12(e)(9)(i), which specified that the surveys should be conducted annually. One comment indicated confusion about the requirement by stating that an annual FDA inspection was not needed if a certified physicist conducted biannual surveys. The other comment asked that the requirement be modified to allow the annual surveys to take place in a year plus or minus a reasonable period.

FDA notes that an inspection is not a survey but rather is a check by an independent authority on how well the facility is meeting the requirements. An inspection and a survey serve different functions and are both required under the MQSA. Furthermore, the inspection does not duplicate the physicist's work. The inspection involves conducting only the tests that provide the most general picture of the equipment performance but also includes review of other aspects of the facilities performance such as personnel qualifications and reporting and recordkeeping practices, which are not considered by the physicist during the survey. Recognizing the unique characteristics of both the survey and the inspection, and the benefits of multiple oversight mechanisms, Congress required that each be conducted annually. Performance of more frequent surveys, semi-annually, e.g., does not eliminate the need for inspections. FDA has retained the requirement for an annual survey in accordance with 42 U.S.C. 263b(e)(1)(B)(iv). This requirement does not prohibit the facility from having a survey more frequently if it wishes. In response to the second comment, FDA notes that it has exercised its enforcement discretion under the interim regulations, and intends to continue to do so under the final regulations, to permit short periods of additional time beyond 12 months for the facility to obtain a survey under certain circumstances. The agency has done so in recognition of the difficulty that facilities that rely on contract physicists have in scheduling surveys. However, this exercise of enforcement discretion in a particular year is not intended to set a pattern that will permit facilities to impemissibly lengthen the timeframes between surveys to longer than annually.

(Comment 537). Several comments were received on the survey report required under § 900.12(e)(9)(iii). One comment recommended that a standard physicist report format should be required to facilitate review. Another stated that there should be provision for identification of units if the facility has more than one unit or has installed a new unit in an old room. A third comment stated that the report should include the calibration dates of the exposure measuring instruments.

FDA recognizes the advantages of a standardized report and in the past has encouraged the use of the report format recommended in the ACR quality assurance manuals. This format includes provision for identification of the unit being evaluated; such information has been and will continue to be implicitly required, because without it, the facility is unable to prove that a particular unit was included in the survey. FDA also believes that there has been a move towards standardization under the interim regulations because reports that inadequately provide the information needed during inspections have created extra work for facilities and physicists who must provide the information. This has led to improvements in later reports. However, while there are advantages to a standardized report, FDA also recognizes the need to allow flexibility in this respect to cover special situations and to permit the use of individual initiative in developing improved formats. The agency concludes, therefore, that it is both unnecessary and needlessly restrictive to require a specific report format by regulation.

Because the calibration requirement for exposure measuring instruments (§ 900.12(e)(12)) is a new requirement, this information has not been checked during inspections under the interim regulations. Because it is now a requirement under the final regulations, FDA expects that, in most cases, this information will be included in the survey report and that there is no need for a specific regulation requiring it to be there. However, if the facility wishes to provide the information in some other format, it will have the flexibility to do so.

(Comment 538). Four comments were related to the requirement of § 900.12(e)(9)(iv) that the report be provided to the facility within 30 days of the survey. One comment suggested shortening the interval to 2 weeks. Another stated that Massachusetts had found that a requirement that the facility's lead interpreting physician sign the report within 30 days had been effective in ensuring that the findings of the medical physicist were implemented. A third comment proposed that the deficiencies noted by the medical physicist be corrected within 1 month. The fourth comment urged that if the report is not received within 30 days, the facility be required to take the equipment out of service. This, it was believed, would stimulate the physicist to be timely.

FDA believes that a shorter time period would be unreasonable in situations where contract physicists might do several surveys in a several day trip before returning to his or her office to complete the reports. The agency also believes that it is common practice that before leaving the facility, the physicist gives a preliminary report to the facility staff, which would include identifying conditions that require prompt action. The new provisions of § 900.12(e)(8), which require correction of certain serious test failures before the failed equipment is used for further examinations, will further stimulate the provision of

preliminary reports. The agency continues to believe, therefore, that the 30-day timeframe is reasonable. With respect to the second and third comments, the agency believes that the new § 900.12(e)(8) adequately ensures that the more serious failures are corrected before the equipment is used again and that all identified problems are corrected within 30 days. A separate requirement is not needed here. With respect to the fourth comment, FDA believes that there is already sufficient incentive for the facility to make sure it receives its report within the 30 days without need for the drastic action suggested.

(Comment 539). The last comment on this paragraph endorsed the requirement in § 900.12(e)(v), that not only the physicist, but anyone who is performing part of the survey under the physicist's direct supervision be identified.

FDA retained this requirement when the regulations were codified.

m. *Mammography equipment evaluations (§ 900.12(e)(10))*

FDA proposed this provision to resolve several somewhat conflicting concerns. The basic goal was to ensure that newly installed equipment or equipment that had undergone major changes is tested for adequate performance by a qualified person before the equipment is used for examinations. However, this goal had to be achieved within the statutory limitations that provide for the issuance of provisional certificates prior to the completion of the survey and that require review of QC data as part of the survey. Such data cannot be generated unless the unit is in clinical use (42 U.S.C. 263b(c)(2)). The agency was also concerned about the costs that might be incurred by a facility that required two visits by the physicist, one visit for the original equipment check and the second for the full survey. There was also concern about the possibility of reduced access attributable to delays in putting the equipment into use due to inability to arrange for a visit by a physicist for some period of time.

Proposed § 900.12(e)(10) was an attempt to balance these conflicting concerns by requiring a mammography equipment evaluation of units or processors that were either new or had undergone major changes before those units were put to use in performing examinations. The evaluations were to be done by a qualified person, who could be a physicist or could be another individual, such as an installer or manufacturer's representative, and any problems found were to be corrected before the equipment was used clinically.

(Comment 540). One comment supported this paragraph as written, but 27 comments opposed allowing anyone but a medical physicist who met the requirements of § 900.12(a)(3) to perform the mammography equipment evaluation. NMQAAC also supported requiring that the physicist perform this evaluation.

In view of these comments, FDA has changed the wording to limit the performance of the mammography equipment evaluation to a medical physicist or someone under the direct supervision of a medical physicist. As noted above, this may mean a delay of some weeks in the use of the equipment at some facilities until a medical physicist can be scheduled for the evaluation. However, the agency has been persuaded by the unanimity of the public comments and the advice of NMQAAC that the benefits of having a medical physicist perform the evaluation outweighs the disadvantage of a possible delay. The agency also notes that by planning ahead, the facility may be able to minimize this delay.

(Comment 541). Several comments addressed the issue of the content of the mammography equipment evaluation. Two comments urged that this be a complete survey but a third noted that the equipment would have to be in use for a period of time before the complete evaluation could be done. Four other comments suggested some specific tests to be included in the evaluation, but two more comments recommended leaving the decision about necessary testing to the person doing the testing.

As noted above, the MQSA provisions relating to provisional certificates and the physical impossibility of checking QC data before the equipment is put into use preclude the possibility that the mammography equipment evaluation can be the full survey required by the statute. Although the agency agrees that it may be beneficial to do a variety of tests at the time of the equipment evaluation, it does not intend to designate particular tests in the regulations. The revised provision simply requires that the evaluations determine if the new or changed equipment meets the applicable requirements of § 900.12(b) and (e), thereby focusing on the primary public health concern, which is to establish that units are not put into clinical use without proper testing. This more general wording, the agency believes, also eliminates the need to consider processors and mammography units separately with respect to this evaluation, as suggested by six comments.

Related to the content of the mammography equipment evaluation is FDA's concern, mentioned earlier, about the expense to the facility if two physicist visits are required, one for a mammography equipment evaluation and another, later, for the survey. The agency's original efforts to reduce costs was its proposal to permit the mammography equipment evaluation to be performed by qualified individuals other than physicists. The revised final regulations eliminate this possibility. In a different approach to limiting costs to the facility, FDA plans to permit the initial survey of the new or changed equipment to be done in two stages. The first stage, the mammography equipment evaluation, will obviously require a facility visit by the physicist. If the facility and physicist can cooperate to produce adequate documents, FDA will permit the second stage, the review of the QC data after it is available, to be done by mail. Presumably, this will cost the facility less than two onsite visits to the facility by the physicist. The agency stresses that this two-stage process is intended to help contain costs associated with a facility's initial survey of new or changed equipment and is entirely optional and within the discretion of the facility and its physicist. The agency will require subsequent annual surveys of that equipment to be done at one time through an onsite visit.

The proposal required a mammography equipment evaluation for new equipment and also after major components of the equipment were changed. FDA specifically asked for comments on what should be considered to be ''major components'' but received relatively few responses.

(Comment 542). One comment suggested processor rollers in the case of the processor. For the X-ray unit, two comments suggested the X-ray tube and one of these went on to add the bucky, the screen-film system, and the photo-timing system. Two comments also suggested changes in the ventilation system because such changes can cause major artifact problems. Another comment simply suggested that repairs by service personnel should require testing.

FDA found these suggestions useful and will take them into account in determining what constitutes a major component. With respect to the regulations themselves, in view of the limited number of comments, the agency decided to continue to keep the wording general.

(Comment 543). One comment opposed the entire idea of a mammography equipment evaluation before the equipment was put into use, stating that it would only increase the cost of installation. Another comment, however, strongly supported the correction of all problems before any equipment was put into use. FDA agrees that there will be some cost associated with mammography equipment evaluations, but believes that the dangers inherit in permitting the use of untested equipment in patient examinations more than justifies this requirement. Therefore, the agency has retained the requirement in the final rules and clarified that the evaluation is also required for new and reassembled equipment, or whenever a major component is changed or repaired.

n. *Facility cleanliness (§ 900.12(e)(11))*

This proposed paragraph required the facility to establish and implement protocols for maintaining darkroom, screen, and view box cleanliness and to document that the protocols were followed.

(Comment 544). Six comments stressed the importance of darkroom, screen, and view box cleanliness, primarily because of the likelihood that dirty conditions will lead to artifacts. Three comments took the opposite position, stating that the section should be deleted due to lack of evidence of a hazard. Seven comments urged FDA to go further and establish protocols for cleaning in the regulations. On the other hand, 13 identical comments questioned whether it would be possible for FDA to establish regulations on cleanliness.

FDA believes that proper standards of cleanliness contribute to quality mammography; e.g., they do reduce undesirable effects associated with artifacts. However, as the agency stated in the preamble to the proposed regulations, there are a variety of cleaning protocols and a variety of circumstances affecting the cleaning needs of a facility. FDA continues to believe that facilities must be given the flexibility to establish cleaning protocols that best fit their needs. The presence and use of such protocols can easily be determined during inspections and their effectiveness, or lack thereof, will be demonstrated by the results of the QC tests, such as the artifact test.

(Comment 545). Six comments stated that FDA was paying attention to disinfecting the equipment but not to screen cleanliness, apparently a reference to § 900.12(e)(13), discussed below.

FDA disagrees with these comments and believes that adequate attention has been paid to both areas. The agency also notes that the infection control requirements will also address the concerns raised by the comment, which stated that cleanliness requirements for bucky and compression paddle and examination room cleanliness should be added.

o. *Calibration of air kerma (exposure) measuring instruments (§ 900.12(e)(12))*

This paragraph, as proposed, required calibration of the instruments used by medical physicists in their annual surveys to measure exposure, at least annually. Ten years after publication of the regulation, additional requirements would have to be met by those doing the calibration.

(Comment 546). Numerous comments urged FDA to change the required frequency of calibration to once every 2 years. A few comments opposed the requirement entirely, while others suggested calibration more frequently than annually. In response to these comments, FDA changed the required frequency to once every 2 years as a normal practice, but also retained the requirement for calibration after a repair of the instrument.

As discussed in connection with the definitions of kerma and air kerma, the agency has also introduced the quantity of air kerma into this rule in accordance with the move towards use of SI units. Also in accordance with the agency cost concerns discussed earlier, the requirements proposed in § 900.12(e)(12)(ii) to be phased-in over 10 years have been eliminated.

p. *Infection control (§ 900.12(e)(13))*

This paragraph was proposed in recognition of the fact that, while transfer of disease caused by blood borne pathogens during mammography has never been reported, it is theoretically possible. Therefore, the agency concluded that appropriate precautions should be taken. Because FDA believes that this concern is not unique to mammography, it did not propose specific requirements for mammography equipment but stated instead that the facility should follow the general requirements for infection control related to medical devices.

(Comment 547). Seven comments opposed this requirement. Reasons given included that it was redundant, unnecessary, and time-consuming; would create needless paperwork; and did not deal with a radiation control problem. Two comments, however, urged additional measures, such as requiring informed consent and the use of protective covers. Another comment warned that any material placed between the breast and the image receptor would cause increased dose and degradation of image quality.

FDA believes that the comments do not provide convincing arguments for a change in the agency's position in either direction. The agency continues to believe that at least a theoretical concern about disease transmission exists and that the best way to deal with this concern is to address it as part of infection control procedures to be followed during the use of medical devices in general.

6. Quality Assurance-Mammography Medical Outcomes Audit (§ 900.12(f))

This paragraph requires that every mammography facility establish and maintain a mammography medical outcomes audit program for followup on mammographic assessments and correlation of pathology results with the interpreting physician's recommendations. This program should be designed to ensure the reliability, validity, and accuracy of interpretation of mammograms.

a. *General comments on medical outcomes audit*

(Comment 548). A single comment was received on the general difficulty in conducting a medical outcomes audit faced by facilities that rely on contract interpreting physicians. Specifically, the comment noted that there would be a higher potential for bias in medical outcomes audits conducted for small facilities that employed a relatively greater number of interpreting physicians.

FDA disagrees that the use of a number of contract interpreting radiologists will necessarily result in biases in medical outcomes data. Data should be calculated both for the aggregate facility data base of patients and again for each interpreting physician. Because the data are to be calculated for individual physicians, any particular set of data that represents unusual or anomalous results will be readily identified and additional calculations can be performed by the facility to project average outcomes without that outlying data. The benefit of tracking these results, therefore, includes the ability to identify problems and find trends. The facility will be required to designate a reviewing interpreting physician to review these data and to notify all interpreting physicians, including contract interpreting radiologists, of both aggregate and individual results. Such analyses may require followup actions, which are to be documented by the reviewing interpreting physician.

b. *Confidentiality*

The issue of maintaining confidentiality of medical outcomes audit information collected by the

facility during its mammography medical outcomes audit was a highly controversial area and generated a diverse number of comments. Five comments stated that FDA should collect audit results and publish the information in aggregate form for the public's information. Two additional comments argued that interpreting physician performance data should be made available to any third party or examinee.

On the other hand, 25 comments urged that FDA ensure confidentiality of medical outcomes audit data either through Federal legislation or under the MQSA. Thirteen comments sought to protect the data by making it available only for internal purposes and restricting its submission to FDA and other agencies. One respondent expressed concerns relating to the use of data by third parties, such as facilities, radiologists, and patients. The comment went on to say that, in the instance of a law suit, all such information would be subpoenaed. Five comments stated that due to lack of common definitions and public understanding of the statistics most likely to be captured in the medical outcomes audit, such data should not be made available to any person not affiliated with the facility. Nine other comments agreed that medical audit data should not be shared with others outside the facility, even though they agreed that valuable use can be made of the medical audit within the facility in assessing the accuracy of interpretations. Two comments argued that, unless false negative cases are required to be included in the medical outcomes audit and also protected from discovery, there will be incentives to conduct poor quality audits. Finally, one comment stated that medical outcomes audit requirements inevitably will increase third-party requests for medical audit data in order to select providers.

FDA recognizes the very sensitive nature of the issue of confidentiality of mammography medical outcomes audit data. Under the final regulations, there are no requirements for dissemination or reporting of the data to public bodies or other agencies, including FDA. There is, however, a requirement that each facility establish and maintain a system to conduct followup and make that system available for review by the inspector. Followup is required for all positive mammograms and for those patients who are known to have developed breast cancer after having had a mammogram at the facility. There is also a requirement for internal facility review of these data. FDA believes these regulations ensure the establishment and use of medical outcomes audit data to help protect the public health without necessarily jeopardizing the confidentiality of such data or the incentives facilities and practitioners have to use these data to improve performance. Future regulations are possible in this area.

(Comment 549). Fifteen comments wondered if radiologists could refuse to allow an inspector to copy audit data in addition to visually reviewing it. As discussed previously, FDA does not intend to have inspectors obtain photocopies of medical outcomes audit information. The agency is requiring inspectors only to verify that systems are in place for the facility's use as part of a quality assurance program (see earlier discussion in the preamble to the proposal at 61 FR 14875).

c. *General requirements (§ 900.12(f)(1))*

This paragraph requires facilities to establish and maintain a system for collection and review of outcome data and correlation of pathology results with initial mammographic results. The active collection and followup of data are to focus on positive mammograms with correlation between pathology results and interpreting physician's initial mammographic interpretation.

(Comment 550). Overall the comments about this paragraph were generally positive. Eight comments stated that the requirement would be beneficial to mammography facilities and staff. A small number of comments advocated that followup data be collected for all abnormal mammograms, including those requiring additional imaging before a final mammographic interpretation can be made.

FDA notes that the current language of the final regulations states that a system is to be in place to collect and review outcome data for all mammograms with required followup for positive mammograms. Although followup is required only for positive mammograms, facilities that wish to follow all their cases are encouraged to do so. Future MQSA regulations may include such a requirement for broader followup, including for those mammograms requiring additional imaging before determination of a final mammographic result.

Followup for patients with abnormal mammographic results has been conducted successfully by several different groups, including the National Cancer Institute Breast Cancer Surveillance Consortium, CDC, individual groups of radiologists, and on a statewide basis in Colorado. Followup for all patients with abnormal mammographic results, or symptomatic for breast cancer, or requiring additional imaging studies was successfully accomplished in Colorado through the Colorado Mammography Advocacy Project (CMAP).

As mentioned previously under the discussion on the use of the mammography medical outcomes audit as an alternative approach to design and process-based regulations, the National Cancer Institute's Breast Cancer Surveillance Consortium has also established a major research project to understand the full effect of breast cancer screening on cancer outcomes. Data on breast cancer screening practices from nine sites across the country are being linked to population-based cancer registries. By 2000, the database will contain information on nearly 3.2 million mammographic examinations and over 24, 000 cases of breast cancer. Standardized procedures and tools were created and are being tested by the surveillance consortium that will assist mammography facilities in data collection and auditing. Results and outcomes of the consortium will help establish performance standards for mammography and FDA will evaluate these for appropriateness for future standards under MQSA.

CMAP is a centralized data management system that conducted followup for all women with abnormal mammograms and women with symptoms of breast changes. CMAP also prompts return for regular rescreening through a series of reminder letters to women and their physicians. This system involves voluntary participation of mammography centers, with most facilities in the greater Denver metropolitan area participating. CMAP services were also offered to some or all patients outside of the metropolitan region. The same tracking and followup and screening reminder methods were used at these facilities as for those in the Denver metropolitan area. Data collection for individual patients, facilities, radiologists, surgeons, and referring physicians is governed by stringent standards for confidentiality. During the 8 years of operation of CMAP, the Program ensured that there were no breaches in confidentiality protocols. Followup includes collection of all information about diagnostic procedures performed to evaluate mammographic abnormalities. Currently, CMAP is tracking more than 200,000 women and more than 300,000 mammograms with approximately 3 percent falling into the ''positive'' category based on radiologists' mammographic interpretation. The system has documented screening

compliance rates in excess of 85 percent and improved outcomes associated with the diagnosis of breast cancer. Specifically, women tracked by CMAP and diagnosed with breast cancer had smaller tumor sizes and earlier stages at detection when compared to a cohort of women with breast cancer who had not received the level of tracking and followup performed by CMAP.

(Comment 551). Twelve respondents supported the FDA requirement for collection of outcomes data, but requested that FDA establish guidelines for the content of the audit and the audit process in order to ensure comparability of medical outcomes data. In contrast, three comments supported the current FDA position to establish only very general requirements for the medical outcomes audit.

In the absence of any consensus standards for either mammography outcomes or data collection methods, FDA has chosen to defer proposing these parameters and methods until more research has been completed and clear guidelines can be formulated for mammography centers.

Despite the general support for the medical outcomes audit, 28 comments expressed concerns that there is no consensus on measures of mammographic efficacy. As discussed above, FDA acknowledges the lack of substantive research on appropriate and accurate measures to assess accuracy of mammographic interpretation and, therefore, has not required specific data to be collected for the medical outcomes audit. Instead, the agency has established a general requirement that mammography facilities have a system in place to collect and review outcome data for all mammograms. Followup is mandatory only for positive mammograms and for patients who were previously screened at a facility and were subsequently found by that facility to be diagnosed with breast cancer.

In addition, the same 28 comments maintained that there was no evidence that performance feedback about mammography outcomes affected the quality of care. In fact, however, the agency notes that there are several articles in peer-reviewed journals indicating that performance feedback is an effective strategy to issue positive behavior change (Ref. 3).

(Comment 552). Many comments expressed concern about the impact on audit results of serving diverse populations of patients. It was recommended that FDA keep such variations in mind when more clearly defined medical outcome standards are established in the future.

FDA acknowledges the importance of this point and will take population diversity into account in the future development of more specific audit parameters.

(Comment 553). Three comments stated that the medical outcomes audit requirement emphasized detection of false positives and expressed the opinion that this was a meaningless outcome. Three more stated that the most important measure was the rate of false negatives.

FDA notes that the final regulations do not require reporting of either false negatives or false positives. The emphasis is on collecting followup data for all patients with positive mammographic findings and for patients who received mammography at a facility and were later determined to have breast cancer. Such followup may yield a number of statistics, including false negatives and false positives.

NMQAAC has suggested that FDA provide reference articles to which facilities could refer if they wanted to compare their own statistics with those of other practices. FDA supports this type of educational outreach and intends to list such references in *Mammography Matters* as they become available. NMQAAC also noted that future revisions of the regulations may require specific performance standards to be issued for mammography once scientific evidence supports such performance standards. The agency agrees that such future developments are possible. However, the current regulation requires followup only for patients with positive mammograms as defined by the assessment categories of ''suspicious'' and ''highly suggestive of malignancy'' and for patients who received mammography at a facility and were later determined to have breast cancer.

(Comment 554). Twenty-seven comments expressed concerns about burdens imposed by the FDA requirement for medical outcomes audit. The burdens included both financial costs of conducting the audit and concerns about staff time to collect the outcomes data. A subset of these comments specifically cited costs associated with the need for sophisticated computerized systems and an increase in clerical staff in order to accomplish the amount of followup required by the regulation.

FDA notes that the number of patients requiring followup (i.e., those mammograms assessed as ''highly suggestive of malignancy'' or ''suspicious'') should be relatively small compared to the general population of women screened at a given mammography facility. In fact, data from CMAP and the other programs cited above suggests that an average of 3.0 percent to 5.0 percent of the total population of patients receiving mammograms at a facility will require active followup. While FDA recognizes that there may be some increase in costs associated with staff time to conduct such followup for all positive mammograms and patients subsequently diagnosed with breast cancer, the benefits of followup are considered to outweigh the costs. In addition, the small number of patients requiring intense followup will not place an undue burden on an individual mammography facility when it is measured against the education and experience acquired by facility personnel. The information gained by staff has been shown to have a positive impact on interpretation skill. Feedback about patients with positive mammograms is extremely important information for both radiologists and technologists. Finally, it was the general consensus of the members of NMQAAC that the benefits of medical outcomes outweighed the costs, especially when one considers the small number of cases the current regulations will affect and data from centralized mammography tracking systems, such as the CMAP, which indicated that costs of followup can be minimized. One Committee member also noted that such followup actions could reduce costs associated with medical liability actions.

(Comment 555). Sixteen comments assumed that the medical outcomes audit would require computerized systems and more clerical help, thereby resulting in increased costs.

FDA notes that a computerized tracking system is not required by the final regulations. In fact, many facilities rely on a manual notecard tickler file to ensure appropriate and timely followup for eligible patients. Some facilities have joined a consortium of mammography centers where followup can be accomplished by a centralized data collection effort. Centralization of followup was designed and implemented very successfully for CMAP, with significant economic benefits and opportunities for data comparisons between one facility and the aggregate of all participating facilities. Utilization of unique identification numbers for patient, facility, referring physician, radiologist, and surgeon preserved confidentiality. Information on the type of data to collect and methods of data collection and interpretation will be forthcoming from FDA.

(Comment 556). Three comments asserted that the responsibility for followup should remain with the surgeon and/or referring physician.

FDA agrees that followup by the referring physician or surgeon may well be the most effective way to communicate with patients and collect outcome data. However, the agency's authority under the MQSA is focused on mammography facilities. FDA cannot establish audit or followup requirements for physicians who do not work as interpreting physicians in mammography facilities.

(Comment 557). One comment suggested that certified facilities be required to share patient outcome data with other certified facilities, especially if that information is necessary in order to complete the medical outcomes audit.

FDA has no evidence at this time that facilities are unwilling to share followup information with other facilities that have treated their patients. Upon implementation of the final regulations, FDA will monitor this cooperation and determine if there is a need for such a requirement in subsequent regulations.

It was requested that FDA define 'correlation' of mammographic results with pathology results. FDA has addressed this in the comments on § 900.2(bb) of the final regulations.

d. *Data collection (§ 900.12(f)(2))*

(Comment 558). This provision requires that data be collected on an ongoing basis for at least all patients with positive mammograms. The majority of the comments related to this paragraph suggested that the regulations require surgeons, referring physicians, and/or pathology laboratories to submit outcomes data to the mammography facility rather than requiring proactive followup by the facility for all positive mammograms.

FDA agrees that such reporting would facilitate the efficient collection of accurate outcomes data. FDA has taken actions to encourage other medical entities to voluntarily provide this data (Journal of the American Medical Association, 1995), but as noted above, FDA's authority under the MQSA focuses on mammography facilities. FDA cannot require other entities or health care practitioners to collect data and forward it to mammography facilities.

(Comment 559). One comment stated that it ''was not right to force a physician to file statistics with FDA just for statistics sake.''

FDA believes that it is important to point out that the final regulations do not require reporting of any medical outcomes audit statistics to FDA. If such requirements are established in the future, it would only be because it was justified by public health benefits and not ''just for statistics sake.''

(Comment 560). A number of comments raised concerns about the medical-legal implications of collecting outcomes data and some of these urged FDA to mandate audit protection for every facility in every state. Concerns were raised that the data could be subject to subpoena, used against facilities in malpractice claims, or evaluated by third-party payers to award contracts. Discussion among members of NMQAAC, on the other hand, indicated that collection and review of data does result in improved breast cancer detection outcomes and can also serve to protect a facility in the instance of a legal claim.

Although State laws on protection of medical audit data do vary, FDA believes such information is protected from use against facilities or physicians in the majority of cases. The Committee supported the regulations as they are currently written. As stated previously, the regulations only require that a system be in place to conduct followup and that such followup would be required for all positive mammograms. The regulations do not require disclosure of any outcomes data to FDA or any other entity outside the facility. The agency has concluded that the final regulations strike the proper balance because the benefit of audits in improving accuracy of interpretation outweigh concerns about forced disclosure to third parties.

e. *Frequency of audit analysis (§ 900.12(f)(3))*

This paragraph establishes guidelines for the frequency of the medical outcomes audit.

(Comment 561). The majority of comments relevant to this point supported an annual audit of medical outcomes, but also recommended that the audit period end 6 to 12 months prior to the date of the audit in order to ensure collection of complete patient information. FDA recognizes the need for adequate time to elapse in order to collect all relevant data. In response to the comments, the provision was amended to clarify that the audit analysis may be completed up to 12 months following the close of the audit period. This additional time for completion of followup was supported by NMQAAC. However, because the requirement is to do an annual audit, a subsequent audit period will be in effect during the time the facility completes followup for the previous medical outcomes audit period.

Comments also recommended requiring quarterly review of audit data by interpreting physicians. FDA established the requirement for annual review of these data in order to maximize the number of cases eligible for followup and data analysis. Facilities are free to review their audit data at more frequent intervals if that is useful or desirable for that practice. FDA notes, however, that quarterly audit review may not yield sufficient numbers of cases for performance of valid statistical analyses.

Finally, one comment asked what was meant by individually and collectively' for review of medical outcomes audit data. FDA has revised the provision to clarify that the medical outcomes audit data is to be evaluated by the reviewing interpreting physician for the entire facility and for each individual radiologist reading mammograms for the facility.

f. *Reviewing interpreting physician (§ 900.12(f)(4))*

This paragraph requires that each mammography facility designate at least one interpreting physician to review medical outcomes audit data at least annually. This individual will also be responsible for analyzing results and identifying issues based on these results and recording any followup actions.

(Comment 562). Eight comments expressed concerns about the utility and feasibility of conducting medical outcomes audit reviews for individual physicians. These comments reasoned that the numbers would be so small that findings would not be of practical or statistical significance, and that such analyses would also be resource intensive.

FDA acknowledges these concerns, but expects that, over time, adequate data will be available for individual interpreting physicians that will become meaningful and will allow tests of statistical significance.

(Comment 563). Five comments supported the proposal to include 'taking corrective action and documenting such actions' in the requirement, while two others argued that this would not always be possible.

Review of these comments and discussions with NMQAAC prompted FDA to change the wording to recognize that the reviewing interpreting physician may not always have authority to institute corrective actions. As revised, the proposed regulation requires the reviewing interpreting physician to document what, if any, followup actions were taken following review of the individual and aggregate medical outcomes audit data.

(Comment 564). Nine comments noted that facility performance monitoring and corrective actions were not defined in the regulations and, therefore, this provision is unclear.

FDA agrees and has deleted these terms in revising the language of this provision.

(Comment 565). Finally, one comment recommended that the reviewing interpreting physician should also be the individual responsible for overall facility quality assurance.

FDA does not believe that this dual role is necessary or beneficial for every facility, e.g., a physician who is best suited for responsibility over audits may not be onsite sufficiently often to also be responsible for overall quality assurance. Although the final rule would permit a facility to designate the same person for both responsibilities, it is not required.

7. Mammographic Procedure and Techniques for Mammography of Patients With Breast Implants (§ 900.12(g))

This paragraph implements the MQSA provisions that require FDA to establish ''standards related to special techniques for mammography of patients with breast implants'' (42 U.S.C. 263b(f)(1)(H)).

a. *Breast implant inquiries (§ 900.12(g)(1))*

As proposed, this paragraph required each facility to have in place a procedure to inquire if an examinee has a breast implant at the time of mammography scheduling.

(Comment 566). More than 110 comments opposed making this inquiry at the time of scheduling. Reasons for the opposition included: privacy concerns of the patient, the fact that the patient may not be the person scheduling the examination, and the belief that the best way to obtain this information is by having the technologist question the patient at the time of the examination. Eleven comments supported this requirement, reasoning that this would aid in efficient scheduling and urged FDA to publicize the need for implant patients to inform the facility of their situation at the time of making an appointment.

After reviewing all comments and discussing this issue with NMQAAC, FDA has revised § 900.12(g)(1) to require all facilities to have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic examination, but not necessarily at the time of scheduling. Those facilities that believe it is important to identify breast implant patients at the time of scheduling, in order for the facility to allot the correct amount of time for the study, are free to do so. The comments indicate that many facilities will choose to use the patient questionnaire to obtain this information or have the technologist question the patient prior to the examination.

(Comment 567). Several comments stated that facilities should have the option of referring breast implant patients to facilities where such examinations are done regularly.

FDA agrees with these comments and notes that there are no regulations requiring facilities to perform studies on patients with implants. For those facilities electing not to perform mammography on patients with breast implants, FDA strongly recommends that they develop a mechanism to inform referring physicians and patients of this fact. This will decrease the chances of such patients arriving at a facility that does not ordinarily perform breast implant studies.

(Comment 568). Two comments suggested establishing a minimum volume for these types of examinations in order to concentrate them at facilities that are the best for this purpose.

FDA recognizes that increased experience with imaging patients with breast implants is likely to develop expertise. However, the agency believes that it is in the best interest of all concerned to have high quality mammography performed in as many facilities as possible. It is possible that one technologist at a particular facility may have had additional training in techniques for imaging such patients and be able to do excellent examinations despite relatively low numbers of such patients. It is not the intent of the MQSA to arbitrarily restrict access to mammography services.

b. *Maximizing the visualization of breast tissue for patients with implants (§ 900.12(g)(2))*

This paragraph requires that patients with breast implants undergoing mammography have mammographic views to maximize the visualization of breast tissue, except where contraindicated or modified by a physician's directions.

(Comment 569). Nine comments stated that it is important to take additional and specialized views of the implanted breast in order to achieve maximum visualization of tissue. The authors asserted that a minimum standard, such as requiring Eklund views, should be set. One contradictory comment stated that requiring mandatory views would cause unnecessary irradiation because not every implant can be displaced as in the Eklund procedure.

FDA and NMQAAC agree that, currently, the Eklund procedures, including appropriate individualized views, provide the best mammographic means to visualize breast tissue for most women with implants. The agency and the committee also recognize that other methods may exist that would be preferable in particular cases. Because breast implant imaging is evolving, the agency believes that it would be premature to limit, by regulation, this imaging to only one technique. FDA does not believe that this regulation, as written, will result in unnecessary irradiation of patients because it allows facilities to customize the study to the individual patient.

NMQAAC recommended deleting the phrase ''and optimize breast cancer detection'' as being redundant. FDA agrees and has deleted the phrase from the final provision.

c. *Onsite supervision of mammograms of patients with breast implants (§ 900.12(g)(3))*

FDA received almost 300 comments opposing this proposal, which would have required that mammograms of patients with breast implants be supervised by an onsite interpreting physician. Reasons for the opposition included: Severe scheduling and access problems if an interpreting physician had to be present, no demonstrated medical need for an onsite physician, and the belief that technologists are capable of performing implant examinations without the supervision of an interpreting physician. Four comments supported the section as proposed, stating that it was important to have an interpreting physician onsite to check the quality of the images.

FDA has been persuaded by the comments and subsequent discussions with NMQAAC that requiring an onsite interpreting physician would result in a decrease in access to high quality mammography services for women with breast implants without a significant improvement in the quality of care. Therefore, FDA has deleted this provision.

8. Consumer Complaint Mechanism—Facility Standard (§ 900.12(h)) and Accreditation Body Standard (§ 900.4(g))

These paragraphs, as proposed, establish a process for facilities and accreditation bodies to collect and resolve serious consumer complaints. It provides patients with a mechanism to report what they believe to be seriously deficient mammography services and gives them the opportunity to have their complaints heard, investigated, and resolved.

Section 900.12(h), under facility standards, establishes requirements for facilities with respect to collecting and resolving serious consumer complaints, while § 900.4(g), under accreditation body standards, establishes requirements for actions that accreditation bodies must take to resolve consumer complaints referred to them.

Many of those who commented on the proposed regulations seemed unaware that different aspects of the complaint mechanism were addressed in these two separate paragraphs, and unaware that both sections should be read with reference to the definitions section of the regulations at § 900.2. Because the comments on these separate provisions tended to be similar, and in order to help illustrate the connection between them, FDA concluded that it would be most efficient to address public comments on the complaint mechanism sections of the proposed regulations as a group.

As the consumer representatives on NMQAAC noted, of all of the comments on the complaint mechanism, only two were from consumers. Almost all of the comments were from representatives of mammography facilities.

(Comment 570). Several comments agreed with FDA that facilities should have the flexibility to develop their own complaint mechanism and institute their own procedures for response and resolution. One comment supported the requirement that facilities develop a system for collecting and resolving serious complaints about mammography services and the proposed definition of serious complaints. Two comments, including one from a breast cancer advocacy organization, expressed support for the consumer complaint provision that FDA proposed.

One comment noted concern that there is no rule requiring feedback by facilities to FDA about an accreditation body. The comment suggested that FDA implement a communication mechanism for facilities to register complaints/comments with FDA about the accreditation body. The comment recommended that the mechanism guarantee followup, similar to the provision establishing a consumer complaint mechanism.

FDA believes mechanisms for facility feedback to FDA already exist. Facilities that wish to comment about accreditation bodies may contact FDA's DMQRP (address above) and will receive a response. In addition, the statutory requirement for FDA to audit the performance of accreditation bodies through inspections of selected facilities establishes additional opportunities for review and feedback.

(Comment 571). Two comments discussed the manner in which accreditation bodies might implement the complaint resolution process. One suggested that serious consumer complaints should be handled by an ACR Peer Review process. Another suggested that accreditation bodies could form boards to receive unresolved serious complaints.

FDA notes that the final regulations prescribe no particular method for accreditation bodies to use, believing that flexibility will permit each accreditation body to establish a system that works best for the facilities it accredits and the patients they serve. Establishing specific groups to review unresolved complaints is one acceptable method for fulfilling this requirement.

(Comment 572). One comment recommended that, because accreditation bodies have no enforcement authority other than to revoke or deny accreditation, FDA or the State certifying entity should retain authority to investigate consumer complaints.

In response, FDA notes that nothing in the MQSA or the regulations precludes FDA or a State from investigating complaints. However, the agency believes consumer complaints will be addressed most effectively and efficiently by a three-tiered approach. First, the complaint should be registered at the facility, where there is the greatest chance for resolution. Second, serious complaints that have not been resolved at the facility should be directed to the accreditation body. And, third, the accreditation body can forward serious complaints to FDA. Although consumers may choose to complain to the facility, the accreditation body, or FDA, the intent of these mechanisms is to resolve difficulties quickly at the level closest to the consumer.

(Comment 573). One comment suggested a name change for the consumer complaint mechanism. The author supported the proposed requirement, but preferred the use of either ''consumer comment mechanism,'' or ''consumer feedback mechanism'' to encourage feedback on positive mammography experience(s).

FDA and members of NMQAAC agree that the term ''complaint'' has negative connotations and may not encourage well-deserved positive comments. The statute, however, requires FDA and NMQAAC to develop a mechanism for the investigation of ''consumer complaints.'' Consequently, FDA adhered to the terminology in the statute.

(Comment 574). FDA received seven comments requesting additional guidance and detail about consumer complaint procedures. Five comments suggested that guidance documents be made available for facilities to follow in generating their system for collecting and resolving complaints, including directions for consumers who wish to file a complaint with the facility's accreditation body. One comment suggested that FDA develop a standardized plan, with appropriate forms to review and evaluate each facility's consumer complaints. One comment supported the proposed definition of a serious complaint, but noted that most complaints deal with Medicare and insurance reimbursements, or lack thereof.

FDA agrees that additional information will be helpful and members of NMQAAC have also strongly recommended that guidance be developed. The agency plans to develop such documents for facilities and consumers.

In reference to discussions in the proposal about cultural considerations, one comment noted that facilities cannot reasonably be expected to develop complaint procedures for all possible language, ethnic, and literacy backgrounds. FDA agrees that to require facilities to make such provisions would pose an undue burden. However, the agency encourages facilities to design their complaint mechanism procedures to be responsive to the particular needs of consumers they serve.

(Comment 575). Fourteen comments stated that the required consumer complaint mechanism increases costs.

FDA believes that the requirements for the complaint mechanism are minimal. Preliminary estimates indicate that the costs for establishing and implementing a system are not significant and that many facilities already have such systems in place. In addition, costs of establishing and implementing such systems are likely to be outweighed by the benefits to the facility resulting from better patient relations, enhanced reputation, and avoidance of costs related to unresolved complaints that may lead to litigation.

(Comment 576). Several comments expressed concern that some consumer complaints could unfairly jeopardize facilities and particular employees. These comments hypothesized a variety of situations: A facility's certification could be threatened by an examinee bent on vengeance (for example, if a false negative mammogram and an error in interpretation constitute serious complaints); certain employees could be singled out any time a complaint is

referred to a higher authority (the accreditation body); the technologist could be falsely accused of a myriad of issues pertaining to patient care. Another comment interpreted the proposed regulation to mean that patients with complaints must be contacted for their opinion on whether the facility's solutions are acceptable to them.

FDA foresees some situations in which a facility's certification may be threatened as a result of consumer complaints. For example, if serious complaints have been continuously ignored or left unresolved by the accreditation body or the facility, subsequent FDA investigations may demonstrate that the facility is unable or unwilling to comply with the MQSA standards. The agency is confident, however, that most facilities will make a sincere and effective effort to respond to valid complaints and does not expect that it will be necessary to consider suspending or revoking certificates for this reason, except in rare cases. In reference to concerns about personnel being unjustly accused, FDA notes that technologists are not ordinarily designated as the individuals responsible for the facility's management and operation. To the extent consumer complaints lead to improvement in performance of individual personnel, the quality of mammography is improved at that facility. With respect to the need to contact consumers about resolution of complaints, the agency believes such communication is a necessary part of resolving a complaint. If consumers believe the facility's solutions are unacceptable, they may contact the accreditation body or FDA, who will try to resolve the issue on a case-by-case basis.

(Comment 577). Seven comments noted their objection to additional policies and procedures for a consumer complaint mechanism. One comment noted that a mandatory facility complaint mechanism is superfluous because effective resolution of patients' complaints is already a component of proper patient care. Another comment noted that each facility can develop its own consumer complaint plan without any guidelines from the MQSA. Fourteen comments suggested that FDA simply accept the policies and procedures for mammography consumer complaints that are currently in use at each facility. If no policy and procedures are in place, the facility should establish one.

FDA agrees that, for the majority of facilities, effective resolution of patient complaints is already a component of proper patient care. In fact, under the interim rules, facilities are required to post an address where complaints can be filed with accreditation bodies, and maintain records of all complaints registered at the facilities. The requirements in the final regulations, therefore, should present little additional burden. Those facilities that already have procedures in place are unlikely to have to make any significant changes. Only facilities that do not have a system in place will be required to make any significant investment of resources. As discussed above, procedures are likely to benefit both the public health and the individual facility.

(Comment 578). One comment suggested that the facility should have the option to ignore a consumer complaint. This comment stated that facilities should be encouraged to handle complaints, but not required to do so.

Under the final regulations, a facility must establish a written and documented system for collecting and resolving consumer complaints. That system may include varying degrees of responsiveness to different kinds of complaints. A complaint about the temperature of the waiting room may be handled differently than a complaint about failure to receive notification of examination results. There may be certain types of complaints under its system that a facility decides do not merit additional resources beyond a verbal acknowledgment or response. However, the system must include a mechanism to provide consumers with a way to register serious complaints with the accreditation body. The consumer can use that information to take serious complaints to the accreditation body and inform the accreditation body that the facility made no attempt to resolve the complaint.

(Comment 579). One comment applauded the consumer complaint mechanism in theory, but questioned the wisdom of permitting the facility to determine whether the complaint is serious. The comment stated that facilities should be required to record all complaints and provide all consumers with directions for filing complaints with the facility's accrediting and/or licensing body. FDA does not believe that the facility independently determines whether the complaint is serious because the definitions of ''serious complaint,'' ''serious adverse event,'' and ''adverse event'' (see § 900.2) are the basis for such decisionmaking. Also, if consumers are not satisfied with the complaint resolution, they may complain directly to the accreditation body. A facility's system may require that records be kept for all complaints and that consumers be provided with directions for filing all complaints with the accreditation body if they choose to do so. However, tracking and providing the consumer with instructions about how to file a complaint with the accreditation body are required under the regulations only for serious complaints.

Nine comments recommended that all complaints should be handled on an individual basis at each facility, and that recordkeeping should be based on the protocol for that facility. Two comments noted the additional amount of paperwork the consumer complaint mechanism would generate, and one of these noted the possibility that facilities would be open to liability because of this mechanism.

FDA agrees that all complaints should be handled at the facility if possible, and that recordkeeping procedures can vary with each facility and each complaint, so long as tracking and accreditation body notification are established for serious complaints. If satisfactory resolution of the complaint cannot be achieved at the facility level, however, the consumer must have the option of taking the complaint to another level. In response to the concern about generation of paperwork, FDA notes that the requirement to track complaints has been in effect under the interim regulations since 1993 without any feedback indicating excessive paperwork. As to concerns for additional liability, the agency and members of NMQAAC have both noted that records that are required to be tracked are more likely to help facilities document that they responded to and resolved complaints. In addition, effective consumer complaint mechanisms allow facilities to identify problems and improve the quality of their services.

(Comment 580). One comment advocated that some safeguard addressing confidentially should be implemented before this and similar recordkeeping requirements are retained in the final regulations. FDA notes that consumer complaints are part of patient records and will be handled by facilities with the same care as other records relative to patients. Accreditation bodies are required to protect nonpublic information they receive from facilities and will not further disclose such information. FDA's public information regulations prohibit disclosure of patient records or information that would identify individual patients.

(Comment 581). FDA did not propose a requirement that facilities post a sign that explains how to file consumer complaints, although NMQAAC members supported such a requirement. Nevertheless, the agency received 28 comments, all on a form letter, opposing any requirement for posting of the complaint process, particularly with respect to addressing complaints to the accreditation body. These comments argued that such a notice will confuse patients and send mixed messages (e.g., this is a certified facility, but here's how to complain). One comment noted that the consumer complaint mechanism needs to be more clearly articulated in order to determine a mechanism for posting. The comment expressed concerns about promoting dissatisfaction with the screening experience.

FDA notes that facilities can develop their own posting mechanism if they chose to do so. In these cases, the facility could use messages such as: ''We care about our patients. If you have comments and/or concerns, please direct them to (the name of the person in the facility who is responsible for complaints).'' FDA notes that the name of the accreditation body is listed on the facility certificate, which the facility is required by statute to post prominently within view of patients.

9. Clinical Image Quality (§ 900.12(i))

This paragraph establishes that clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by the facility's accreditation body.

This requirement did not appear as a separate provision in the proposal but was added to the final regulations to emphasize that adequate clinical image quality is to be maintained by the facility on an ongoing basis and is not something to be achieved only at the time of accreditation. FDA recognizes that this requirement may appear unnecessary or redundant. The stated purpose of the MQSA, to establish national uniform minimum quality standards for mammography facilities, presumes that all facilities will produce adequate mammograms on a regular basis. Specific statutory provisions, such as those requiring random clinical image review by accreditation bodies and the establishment of quality assurance programs at each facility to ensure clarity of images, reflect the drafters' intent to ensure quality mammograms for every patient. In addition, the interim regulations issued by FDA and these final regulations establish and support the need for maintenance of adequate clinical image quality at all times. However, FDA's experience with implementation of the interim regulations, and the impression the agency has received from some of the public comments, suggests that some facilities may view clinical image quality as important only or primarily in connection with the accreditation process. The agency has concluded that this critical standard for quality mammography should be stated explicitly in order to emphasize its critical importance and eliminate any chance of misunderstanding.

10. Additional Mammography Review and Patient Notification (Proposed § 900.12(i) (Final § 900.12(j)))

This paragraph requires a facility to cooperate with FDA in the investigation of concerns about the quality of the mammography performed by that facility and in notification of patients or the public, should the investigation justify such notification. As the result of the addition of the new § 900.12(i), Clinical image quality, this paragraph is now § 900.12(j) in the final regulations. The provision has been modified from the original proposal to clarify that this type of review is different from those performed either for accreditation, reaccreditation, or for random clinical image review. Additional mammography review is to be used in those cases where FDA has reason to believe that mammography quality has been compromised and may present a serious risk to human health. Depending on the individual circumstances, this review may be an onsite evaluation or may be performed through the mail. Procedures for performing additional mammography review will be developed by the accreditation bodies and approved by FDA.

If the agency determines that any activity related to the provision of mammography at a facility presents a serious risk to human health, § 900.12(j)(2) requires a facility to notify patients, their designees, their physicians, or the public of actions that may be necessary to minimize the risk. Such notification may be warranted, e.g., in cases where diagnoses of possible malignancy may have been missed due to grossly inadequate performance on the part of the facility. Patients, their designees, health care professionals, or the public may have to be notified so that they may take appropriate remedial action. For example, affected patients may wish to repeat examinations at another facility or a member of the public may be able to contact an otherwise unreachable patient.

(Comment 582). While seven comments supported these requirements as originally proposed, the authors of 26 other comments were concerned about possible abuse of the provisions. These comments requested more information and clear guidelines on how ''serious risk to human health'' would be determined and how the regulation would be implemented. One comment stated that the entire section was not needed and should be deleted. The authors of 25 comments stated that this section sounded like a consent decree without an appeals process. The comments also stated that the intent of this section was unclear.

FDA notes that even comments that expressed concern generally supported the need to investigate and to take appropriate action at facilities where there is a serious risk to human health. In response to specific comments, the agency first notes that patient notification will not always be an appropriate corrective action, even in cases where mammography services have been inadequate. In some cases, patient notification could result in unnecessary patient anxiety, without providing the patient with any plan of action that the patient could take to minimize her risk. The agency recognizes the important consequences to the patients, the public, and the facility of pursuing patient notification and would not initiate such action without full consultation with the accreditation body and the facility and only following review of the additional mammography review performed by the accreditation body.

Although NMQAAC agreed that the agency should exercise this authority with respect to facilities that are performing poorly, members of NMQAAC were unable to reach a consensus on guidelines for initiating patient notification. FDA's experience under the interim regulations may reassure facilities and the public that patient notification is not requested unless FDA has evidence, including review of clinical images by the facility's accreditation body, that indicates there is a strong likelihood that a significant number of mammograms taken by the facility were inadequate. In any given situation, notification will only be appropriate where the benefits of providing notice to women, who may wish to repeat the exam, outweigh any resultant risks, such as patient anxiety or the possible disincentive for future mammography screening. Because of the number of variables involved in any particular situation, FDA believes that the decision as to when a facility has sufficiently

serious problems to warrant patient notification is best made on a case-by-case basis. In the past 2½ years, two facilities have instituted limited patient notification after an investigation by the accreditation body and FDA.

The intent of this section is to assure the public that in those cases of suspected compromised mammography quality, an investigation is performed, and depending on the results of that investigation, appropriate corrective action is taken. If patient notification is the corrective action recommended by the accreditation body and required by FDA, the facility will have every opportunity to participate in designing and implementing that notification. As with any adverse accreditation body or FDA action, the facility has the right to have a determination about patient notification reviewed and appealed within the agency. If the facility does not voluntarily come into compliance or take steps the agency has determined are necessary to ensure quality mammography at that facility, FDA can initiate suspension or revocation of the facility's certificate. In those circumstances, the facility is entitled to a hearing under part 16 of the agency's regulations (see § 900.14) and hearing decisions are subject to judicial review. Contrary to the opinion of many respondents, therefore, FDA's determination that patient notification is necessary is subject to review and appeal.

(Comment 583). One comment opposed this section, asserting that FDA already performs clinical image reviews by randomly notifying the facility that they have so many days to send in certain mammograms.

FDA notes that the author of this comment mistakenly believed that random clinical image review and additional mammography review were the same. As previously stated, these two reviews are performed differently and address different issues and problems. Random clinical image review is performed as an evaluation tool by accreditation bodies in an effort to audit their own performance, and the performance of facilities they accredit. Additional mammography review is to be performed only in those cases where FDA believes there has been a compromise of quality sufficient to pose a serious risk to human health.

(Comment 584). Two comments stated that FDA should ask the accreditation body to investigate questionable facilities, but that the type of evaluation and the final decision should be left up to the accreditation body.

FDA continues to work closely with the accreditation bodies to coordinate all activities, especially those related to image review and mammography quality. Accreditation bodies are critical in establishing processes and parameters for additional mammography review at any particular facility and may be the first entity to discover information that indicates such a review is necessary. Nevertheless, decisions about whether additional mammography review or patient notification are necessary ultimately must rest with the agency.

(Comment 585). One comment questioned why FDA would not start this process as soon as a facility fails accreditation due to clinical image review.

FDA responds that accreditation clinical image review is an evaluation of the ''best'' images that a facility can produce and is scored against the accreditation body's highest standard. Failure to achieve the high quality standard does not necessarily mean that the facility's average images are of a quality likely to result in the misdiagnosis of significant abnormalities.

It is FDA's view that failure of accreditation or reaccreditation clinical image review does not automatically indicate that the facility's overall quality level has been compromised to such an extent that there is a serious risk to human health. Unless there is other information indicating such a risk, the agency does not intend to apply § 900.12(j) to this circumstance. The initiation of additional mammography review under this section is primarily intended to protect the public in circumstances where there is reason to believe an accredited facility is practicing in a way that may cause serious harm.

*M. Revocation of Accreditation, and Revocation of Accreditation Body Approval (§ 900.13)*

This provision describes the procedures that FDA will follow in the event a facility's accreditation is revoked by its accreditation body (§ 900.13(a)). It also outlines the facility's responsibility if FDA withdraws approval of its accreditation body (§ 900.13(b)). No comments were received on § 900.13(b).

(Comment 586). One comment supported § 900.13(a) as written while another comment stated that this section is unclear, and asked whether a facility is allowed to conduct mammography without accreditation. Another comment suggested that no FDA certification should continue in force after an accreditation body has revoked the accreditation of a facility.

FDA issues certificates, and only FDA can determine when a certificate is no longer in effect. Loss of accreditation does not automatically mean the loss of certification. In certain unique circumstances, a facility may remain certified though it lacks accreditation. For example, a facility may be certified through a provisional certificate to perform mammography before it is accredited (42 U.S.C. 263b(c)(2)) or retain its certification for some period of time following FDA withdrawal of its accreditation body's approval (42 U.S.C. 263b(e)(2)). Under the MQSA, if an accreditation body revokes the accreditation of a facility, the certificate remains in effect until such time as may be determined by FDA (42 U.S.C. 263b(e)(5)). FDA interprets the statute to give the agency discretion to find that the certificate should no longer be in effect once accreditation has been lost or to permit the facility to continue to perform mammography for some period of time following loss of accreditation. The language in the final regulation has been amended to reflect this discretion.

After revocation of a facility's accreditation, FDA may conduct an investigation into the reasons for the revocation. Following the investigation, the agency may take whatever action or combination of actions will best protect the public health, including the establishment and implementation of a corrective plan that may permit the certificate to remain in effect while the facility seeks reaccreditation. (In the event that the investigation convinced the agency that revocation of accreditation was not justified, FDA would have discretion to continue the certificate in effect while the original accreditation body reinstated the facility or another entity provided accreditation). Anytime FDA determines that the revocation was justified and the certificate should not continue in effect, the facility that has lost its accreditation may no longer perform mammography. The final regulation has been amended to clarify that a facility whose certificate is no longer in effect must cease to practice mammography.

(Comment 587). Three comments concerning this provision appear to have confused revocation of accreditation with revocation of certification. One suggested making the accreditation bodies responsible for appeals of revoked certificates, and two described facilities that purportedly were unable to operate for 2 years as the result of revocation of their certificate due to a single flawed image or the recommendation of the facility's accreditation body.

FDA does not have enough information about the specific cases referenced in the last comments to respond, except to note that an accreditation body does not have authority to revoke a certificate. In response to the first comment, the agency reiterates that suspension or revocation of accreditation is the responsibility of the accreditation body, and each accreditation body is required to have internal appeals procedures available to all the facilities it serves. Suspension of revocation of an MQSA certificate, however, is the responsibility of FDA. Such suspensions and revocations are governed by 42 U.S.C. 263b(i) and the regulation implementing that section in § 900.14. An accredited facility whose certificate FDA is seeking to suspend or revoke is generally entitled to a hearing before that action is taken in accordance with 42 U.S.C. 263b(i) and § 900.14. The agency wants to take this opportunity to clarify, however, that a facility whose certificate FDA determines to be no longer in effect because its accreditation has been revoked is not governed by 42 U.S.C. 263b(i) or § 900.14. In accordance with 42 U.S.C. 263b(e)(5), the certificate of a facility whose accreditation has been revoked remains in effect only until such time as determined by FDA. Although such a facility will be entitled to an opportunity for a timely hearing following a determination by FDA that the certificate is no longer in effect, it may not continue to practice mammography in the interim.

*N. Suspension or Revocation of Certificates (§ 900.14)*

This section sets forth the conditions under which FDA may suspend or revoke a facility's certificate.

(Comment 588). One comment supported this section as written, while another recommended that this section be revised to include the MQSA provision which authorizes States to conduct certification duties.

As noted earlier in this preamble, the subject of States as certifying bodies is beyond the scope of these regulations. Preparations are under way to draft regulations that will govern State agencies that wish to become certifying bodies.

(Comment 589). One comment recommended changing the word ''determines'' to ''believes.''

Suspension or revocation of a facility's certificate is an action against the facility that should be based on more than ''belief.'' FDA does not intend to take such action without making a determination that it is warranted.

Because there were so few comments on this section, it has been codified basically as proposed. The discussion in the preamble to the proposal at 61 FR 14877 through 14878 describes the provisions of this section in detail. FDA has added failure to provide information, reports, or records ''to the accreditation body'' as an additional grounds for suspension or revocation in § 900.14(a)(3). The agency has made this change to ensure that accreditation bodies have access to records, including clinical images, that are necessary for review. In many circumstances, the accreditation body's access to records is essential for it to fulfill its obligations under the statute and to advise FDA with respect to potential enforcement actons. A facility that refuses to supply such records makes it difficult, if not impossible, for the accreditation bodies and FDA to efficiently investigate or monitor mammography practices at that facility.

*O. Appeals of Adverse Accreditation Decisions that Preclude Certification or Recertification (§ 900.15)*

The title of this provision has been changed to better reflect the fact that it describes the procedures for appealing adverse accreditation decisions that preclude a facility from becoming certified or recertified.

(Comment 590). One comment supported this section as written, and another comment questioned whether a facility can submit additional information in its appeal to FDA, noting that ACR does not consider any additional information from a facility and bases its appeal findings on rereview of the films from the facility that were originally evaluated.

When appealing an adverse accreditation decision, FDA will consider and evaluate any information provided by the appealing facility that may bear on the outcome of the appeal, in accordance with the governing regulations identified in the next paragraph.

(Comment 591). One comment suggested adding ''or reaccredited'' in addition to, ''has failed to become accredited.''

FDA agrees that the addition of ''reaccredited'' would add clarity. Another comment recommended that there be a timeframe for appeals. The MQSA establishes that the procedures in 42 CFR part 498 are to be followed by FDA for appeals. These regulations contain the timeframes to be followed for appeals under the MQSA.

*P. Appeals of Denials of Certification (§ 900.16)*

The comments that requested clarification about the relationship between revoked accreditation and continued certification encouraged the agency to explicity address the issue of facilities that have received accreditation but are denied a certificate. FDA has added a new provision to clarify that the statute provides the agency with discretion to deny certification to a facility that has been accredited. As discussed previously in connection with the section on reviewing applications for certificates, FDA ordinarily will issue a certificate to a facility that has proof of accreditation by an approved accreditation body. This has been the agency's practice in the past and the agency intends to continue its reliance on the professional bodies that are expert in these reviews.

However, there may be situations when the agency has access to information that was not available to the accreditation body or when the agency has other reasons to disagree with that body's determination that the facility applying for a certificate will practice quality mammography. In these unusual circumstances, FDA has authority to deny a certificate. The new provision sets forth the grounds that FDA will use as the bases for such denials: A finding that the facility is not likely to comply with the quality standards; a finding that the facility is not likely to permit inspections or provide access to records and information in a timely fashion; or a finding that the facility was guilty of misrepresentation in obtaining accreditation. These grounds are parallel to those that are the statutory bases for suspension or revocation of a certificate. FDA believes that it is in the interest of public health to ensure that such facilities are not permitted to begin practicing mammography rather than automatically granting a certificate that the agency must later seek to revoke.

The new provision also provides appeal rights for facilities that are denied a certificate. These procedures are the same as those set forth for reconsideration and appeal of an adverse accreditation decision in § 900.15. The procedures are mandated by the statute under 42 U.S.C. 263b(d)(2) and include the right to request a formal hearing from the Departmental Appeals Board of the Department of Health and Human Services.

*Q. Alternative Requirements (§ 900.18)*

Section 900.18 establishes procedures for approval, extension, and withdrawal of alternatives to the quality standards of § 900.12. Such alternatives can be approved if, among other things, the alternatives provide at least as great an assurance of quality mammography as the original standards. The alternative requirement procedure allows the agency to permit the practice of mammography to benefit rapidly from improvements and advancements without the need to first go through the often lengthy process of amending the regulations. When added to the interim requirements through the amendments of September 30, 1994 (59 FR 49808), no public comments were received. This section was incorporated into the final regulations with only minor changes. A few comments were received.

1. General Comments on Alternative Requirements

(Comment 592). Two comments supported this section, one referring to it as a ''most sensible approach,'' but urged monitoring of the use of the alternatives after approval. A third comment suggested that manufacturers be required to provide documentation of approved alternatives to potential purchasers and that copies be available at the facility for review by the physicist and the inspector. A fourth comment urged removal of this section, stating that no variation in meeting the requirements should be allowed.

FDA believes that this process is needed to avoid the danger of discouraging advances in mammography and freezing technology at the present level. If the standards had to be amended to permit use of an advance in methods, training, or technology, the time required for the amendment might well discourage members of the public from attempting improvements. The agency does not believe that it is necessary to make the third comment a regulatory requirement. Manufacturers will find it difficult, if not impossible, to sell equipment that does not meet the requirements or an approved alternative. Because facilities will demand such documentation and will be required to produce it to pass surveys or inspections, FDA concludes there will be sufficient incentive to provide documentation without issuance of a regulation. The agency also notes that copies of applications, amendments, and extensions of alternative standards will be available to the public in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The Dockets Management Branch is open to the public between 9 a.m. and 4 p.m., Monday through Friday.

2. Approved Requests for Alternative Standard Notification (§ 900.18(d)(2)(ii))

(Comment 593). One comment recommended that the justification level for an alternative requirement in this paragraph should be changed from the benefit being so great that the time required (typically more than 1 year) for an amendment would be ''an unjustifiable risk to human health'' to a standard that established that the alternative requirement ''provides a benefit to human health.''

FDA believes that the criterion suggested by the comment could be too low for some ''benefits,'' and has retained the provision as proposed.

3. Summaries (§ 900.18(d)(3))

(Comment 594). One comment stated that the requirement for providing summaries of alternative standards to NMQAAC should be deleted because NMQAAC does not have authority to approve or reject actions of FDA in such matters.

FDA agrees that NMQAAC does not have approval authority in such matters, but it does have the responsibility to advise FDA on matters related to FDA's development and implementation of standards. Because the agency cannot gain the benefit of this advice on alternative requirements without informing NMQAAC about the alternatives, FDA does not accept this comment.

4. Applicability (§ 900.18(f))

This paragraph describes the applicability of an alternative requirement. The proposal limited the use of the alternative to the applicant, with the exception of alternative requirements approved for manufacturers of equipment, which would apply to all users of the equipment. Under the proposal, others desiring to make use of other alternative requirements would have to apply separately.

(Comment 595). Four comments stated that FDA should reserve the authority to extend any approval beyond the applicant. A fifth comment went further and advocated automatic extension of an approved alternative requirement to all interested parties. FDA originally placed the limitation on the approval of alternative requirements in order to assure itself that the conditions that prompted the approval of the original application also applied for other applicants.

In light of these comments and after further consideration, the agency has concluded that the limitation would impose an unnecessary resource burden on applicants and FDA. Such a burden is not warranted by the low probability that an approved alternative requirement should not be extended to other interested and similarly situated parties. However, because the program is relatively new and the circumstances that may trigger requests for alternatives are so varied, FDA has concluded that it should review the appropriateness of each possible extension instead of making it automatically approved as suggested in the fifth comment. Accordingly, § 900.18(f) has been revised to permit expansion of the approval of the alternative requirement to other entities, but only after FDA has determined that this would be an effective means of promoting the acceptance of measures to improve the quality of mammography.

5. Other Changes

FDA has also made a change in the administrative procedures included in § 900.18, realizing that the level of delegation of authority to approve alternative requirements may vary with time or organizational changes. Thus, the specific references to approval by the Director of DMQRP have been replaced by general references to approval by FDA.

*R. Conforming Amendments*

Conforming amendments were made to 21 CFR 16.1 to add §§ 900.7 and 900.14 to the list of provisions under which regulatory hearings are available.

## IV. Environmental Impact

The agency had determined under 21 CFR 25.34(c) that this action as proposed 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.

## V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits

(including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The Unfunded Mandates Reform Act requires (in Section 202) that agencies prepare an assessment of anticipated costs and benefits before enacting any rule that may result in an expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation).

The agency has conducted analyses of the final rule, and has determined that the rule is consistent with the principles set forth in the Executive Order and in these statutes. FDA's analysis, as summarized in the remainder of this section, demonstrates that the final rule constitutes an economically significant rule, as described in Executive Order 12866. The agency has further determined that the final rule may have a significant economic impact on a substantial number of small entities. This discussion, therefore, along with the other relevant sections of this preamble and the agency's final Economic Impact Analysis (available at the agency's Dockets Management Branch), constitute the agency's final regulatory flexibility analysis as required under the Regulatory Flexibility Act. Similarly, because this rule is expected to result in expenditures that exceed $100,000,000 in at least 1 year, these documents also comprise the agency's assessment of anticipated costs and benefits under the Unfunded Mandates Reform Act. The final economic impact analysis also includes all references.

FDA presented a summary of its preliminary economic analysis in the preamble to the proposed rule (61 FR 14856). That summary discussed the potential costs and benefits of the proposed rule and described the findings of a more detailed industry analysis conducted by FDA's contractor, the Eastern Research Group (ERG). In response, the agency received numerous comments that addressed economic issues. FDA has examined and evaluated the reasoning and data presented in these comments and has incorporated many of them into its revised analysis of the final rule. The following discussion provides a summary of these impacts and presents the agency's responses to the relevant public comments.

*A. Incremental Costs*

For its analysis of the incremental costs of the proposed regulation (''Cost and Benefit Analysis of Regulations Under the Mammography Quality Standards Act of 1992''; preliminary final; March 14, 1996), FDA relied on agency experts and technical consultants to develop a broad profile of mammography facilities and to identify the type and cost of the additional equipment and procedures that would be needed to bring the affected facilities into compliance. That analysis found that the proposed rule would impose annualized industry costs of approximately $61.4 million. Upon review of the resulting public comments, FDA has maintained the basic methodology for these estimates, but updated or otherwise revised a number of the input variables.

The full details of the cost estimates for these final regulations are presented in the agency's final Economic Impact Analysis, which is available for review at the Dockets Management Branch and at FDA's home page on the World Wide Web (www.fda.gov) the analysis addresses only those costs that would not have occurred in the absence of these final regulations. The estimates assume that at a minimum mammography facilities are already complying with the agency's current interim regulations and that a typical facility will comply with each requirement of the final regulation by selecting the least costly method of compliance. Current facility compliance levels for the industry were derived for early provisions of the final regulations from published data services or interviews with experts in mammography. The cost estimates are based on a facility cost model that analyzes the inputs to a mammographic examination (e.g., professional time, amortization of fixed equipment costs, variable costs of supplies) and derives the contribution of each activity to the average cost of conducting a mammographic screen. The required capital costs were developed from an industry wide inventory of existing equipment stock, which allowed FDA to estimate the percentage of equipment that will need to be modified or replaced. The compliance cost attributable to equipment requirements was calculated by including the value that this equipment will lose (based on years of remaining asset life) and the cost of retrofitting, if possible. The aggregate costs were modeled over a 10-year analysis period and allocated among the industry sectors based on facility screening volumes. This method allowed FDA to analyze the effect of compliance costs on small volume and large volume facilities.

The analysis projects that yearly expenditures for compliance by mammography facilities will range from a high of $156.2 million during the second year of implementation to $9.5 million during the tenth year, with the variation reflecting the phased implementation dates for the individual requirements. On an annualized basis (over the 10-year period at a 7 percent discount rate), the yearly costs will equal about $38.2 million. Over the full 10-year period, the combined expenditures and lost resources for the largest cost element (replacement of mammography units with units meeting technical or quality assurance standards) will total more than $241 million and contribute approximately $28.5 million in average annual costs (75 percent of the total average annual costs). The other major annual cost components include medical records and reports, $4.6 million; quality assurance systems, $3.4 million; personnel qualifications, $1.6 million; and consumer complaint mechanisms, $0.1 million.

*B. Incremental Benefits*

The benefits of the final regulations will result from improvements in mammography quality and include: (1) Additional life-years (or quality adjusted life-years (QALY's)) and reduced costs of cancer treatment gained by earlier stage identification of breast cancers, and (2) less anxiety and stress and reduced cost of followup diagnostic mammographic screens and other diagnostic procedures gained by fewer false abnormal screens. While data limitations preclude FDA from developing a precise estimate of the magnitude of these benefits, the agency has constructed an impact model that projects the expected health and cost outcomes under various scenarios of plausible mammography quality levels. This model, which forecasts breast cancer outcomes based on tumor stages at time of initial identification, is summarized below and fully described in the agency's aforementioned final Economic Impact Analysis.

1. Baseline Estimates

The patient population affected by the regulation includes all 79.3 million women age 30 or older. Applying age-specific cancer incidence rates to the number of women in each 10-year age cohort projects approximately 180,600 new breast cancer cases annually, of which about one-quarter may ultimately prove fatal.

About 90 percent of the 25 million mammography procedures performed each year are for screening procedures in asymptomatic patients. Thus, FDA's impact model assumes a base of 22.5 million annual screens and 2.5 million annual diagnostic (or subsequent) mammograms in symptomatic patients. Of the 22.5 million screens, approximately 5 million (22 percent) are for women over the age of 65 and 2.7 million (12 percent) are for women younger than 40. The remaining 14.8 million annual screens are distributed by size of each 10-year age category. The age-specific cancer incidence rates within each age cohort indicate that about 56,900 of the 22,500,000 annual screens are for women with breast cancer and 22,443,100 are for women without breast cancer.

Although the benefits of the rule derive from increases in the quality of mammography, the quality dimensions are very difficult to measure. Each mammogram is unique because each patient is unique and many factors contribute to quality, including those that are not affected by these regulations. While other measures have been suggested (e.g., cancer yield and PPV), FDA's impact model relies on a combination of sensitivity and specificity levels to represent average mammography quality. The sensitivity of any diagnostic test is the proportion of the tested, diseased population that is correctly identified as diseased. Thus, test sensitivity addresses the problem of false negatives. The specificity of a test measures the proportion of nondiseased patients who are correctly identified as not having the disease. Thus, test specificity addresses the problem of false positives.

If both sensitivity and specificity improve toward 100 percent, the proportion of ''incorrect'' mammograms decreases. Although improvements in one measure may come at the expense of decreases in the other, as certain technical changes can tradeoff sensitivity for specificity, FDA finds that the input changes required by this regulation will raise the national average of both measures. Thus, the agency's impact model measures quality improvement as the percent decrease (expressed as a percentage over the current level) in the number of incorrect diagnoses, both false positives and false negatives.

Estimates of the current national average levels of mammography sensitivity and specificity are approximate representations, because they reflect literature examinations based on different patient populations, time periods, and definitions. Current sensitivity measures in community settings have ranged from 53 percent to as high as 90 percent and specificity measures have reached as high as 99 percent. However, several studies indicate that mammography facilities in research/academic settings have sensitivity and specificity measures that exceed most ''typical, community facilities'' by 7 to 13 percent. Based on these studies, FDA's baseline estimates assume that current national levels of sensitivity and specificity average 80 percent and 90 percent, respectively. The calculations use age-specific rates, because breast tissue density varies by age of patient.

The estimated 80 percent sensitivity rate implies that while 45,400 of the estimated 56,900 annually screened women with breast cancer currently receive a true positive result, 11,500 receive a false negative result. Thus, FDA estimates that each year, mammography fails to identify breast cancers in an estimated 11,500 screened women. The agency's impact model, which relies on a distribution of identified cancers by development stage and SEER incidence rates for both screened and nonscreened populations, predicts that about 4,300 of these 11,500 women will die of breast cancer within 20 years. The model implies that perfect mammography would prevent about 1,200 of these fatalities. FDA recognizes that perfect mammographic screening is not yet technologically achievable, but the agency is convinced that mammography sensitivity rates can be significantly improved, thereby avoiding a substantial number of these premature deaths.

Economic literature includes many attempts to place a dollar value on mortality avoidance for the purpose of conducting cost/benefit analysis. A common methodology estimates society's willingness to pay to avoid the risk of a statistical death as evidenced by wage premiums necessary to attract employees to riskier occupations. These data contain considerable variability, but appear to average about $5 million per death avoided. Thus, for illustrative purposes, FDA's analysis assumes a $5 million value to represent the societal benefit of preventing a premature death. The value of a life-year was estimated at $368,000 and the value of a quality-adjusted life-year at $373,000.

FDA also believes that the improved mammography quality gained by the final regulations will significantly reduce the rate of false positive results. The above methodology indicates that 22,443,100 women without breast cancer are screened annually. Consequently, a baseline specificity measure of 90 percent implies that 20,184,600 will receive true negative results, but 2,258,500 others will receive false positive results. FDA estimated the cost of the anxiety and increased stress associated with these false positive screening results by assessing the contribution of psychological well-being to the overall quality of life.

The time between a patient notification of a positive screen result and the subsequent identification through a followup diagnostic mammogram was assumed to take about 1 month. The cost of enduring this anxiety was assumed to detract from the value of a quality-adjusted month value of $31,100, i.e., $373,000 ÷ 12. Research indicates that mental focus and psychological well-being affected by a major life crisis can contribute approximately 8 percent to the overall quality of life. Worries about health, illness, and well-being may account for approximately one-sixth of the stress that would constitute a major life crisis. To assess the potential effect, FDA's impact model assumes that 25 percent of those patients who receive false positive results would be willing to pay about $415 ($31,100 x .08 x .167) to avoid the stress and anxiety of a false positive mammogram.

FDA also found that cancer treatment costs vary by stage of detection, from annual costs of $18,900 for the earliest stage to $50,000 for the latest stage. Other components of FDA's model address patient noncompliance with screening results due to fear or denial. Diagnostic mammography readings were assumed to follow positive initial screens, and additional followup diagnostic procedures were assumed to follow positive diagnostic results and to identify lesions that were present without screening. Based on limited data, FDA's model assumes that a small number of those patients with positive screens do not seek further treatment. Figure 1 illustrates the model components and baseline estimates.

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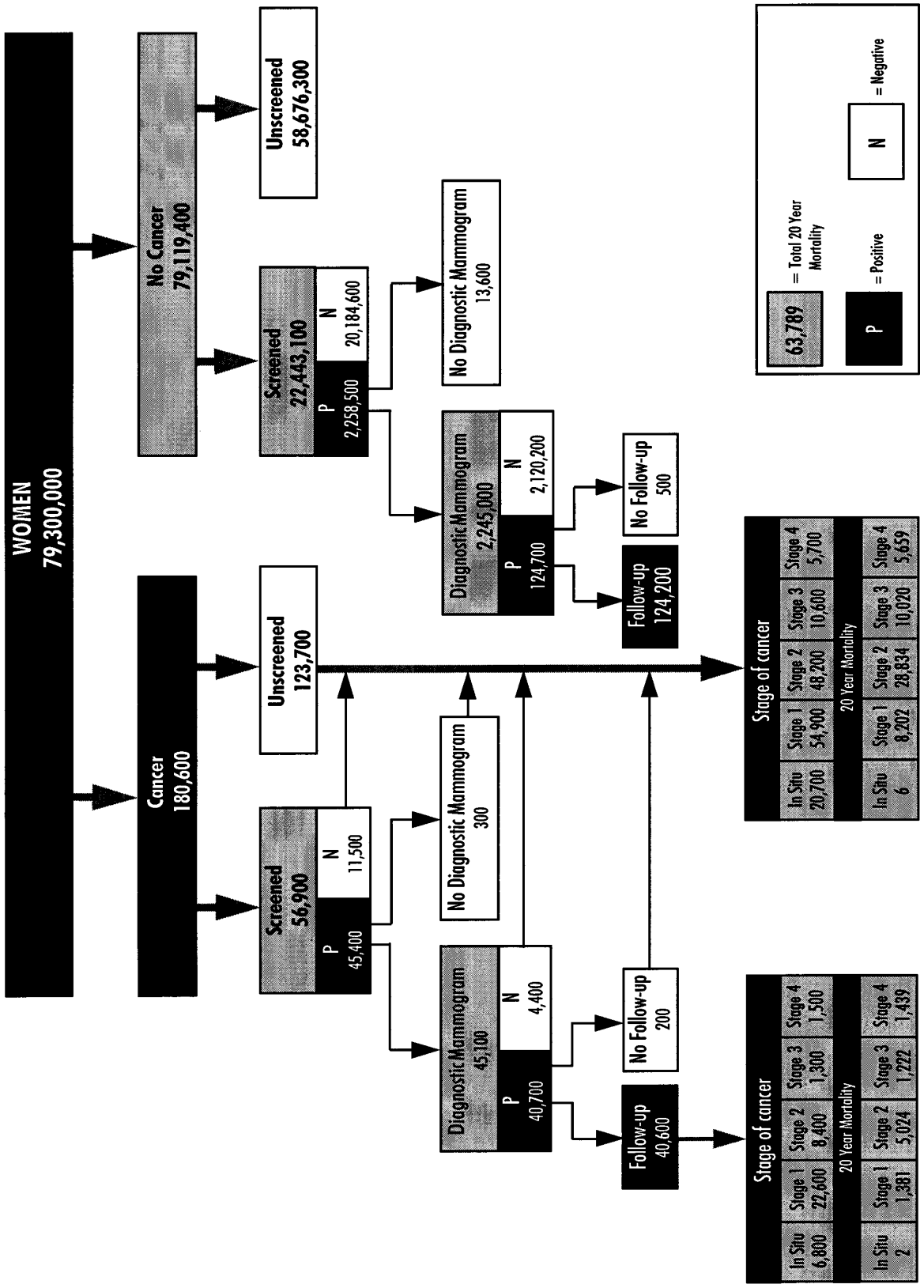


**Figure 1. Baseline Model.**

**Note: Totals may not add due to rounding**

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2. Regulatory Impacts

The agency also finds that the impact of these regulations could affect the demand for mammography. One study found a price elasticity of approximately -0.2 for outpatient well care. As the rules will likely raise mammography prices as well as costs, FDA incorporated this price elasticity into its impact model. On the other hand, improved mammography quality will have a positive effect on mammography demand. Assuming that the demand for mammography for a subset of potential patients exhibits a unitary elasticity with respect to quality, FDA's impact model finds that a 5 percent increase in mammography quality would roughly offset the above price-induced decline in demand, with the net change less than .03 percent.

Because of the difficulty in assessing the impact of the regulations on mammography quality, no public comments attempted to quantify the likely health outcomes. Similarly, FDA cannot predict the precise magnitude of the quality improvement that will be generated by these final regulations. FDA believes, however, that the mammography quality improvements will be substantial and that gains as small as 5 percent (i.e., reducing the proportion of incorrect procedures by 5 percent by increasing average sensitivity levels from 80 percent to 81 percent, and specificity levels from 90 to 90.5 percent) would produce substantial net benefits. The results of this analysis are shown in figure 2. For example, when compared to the baseline data (figure 1), the number of earlier cancers detected due to a 5 percent improvement in mammography sensitivity would prevent about 75 women per year from dying of breast cancer within a 20-year period. At $5 million per life saved, the discounted value of this outcome is about $234 million per year. Alternatively, the model shows that a 5 percent quality improvement would bring an annual increase of about 410 discounted QALY's valued at $153 million. Thus, FDA estimates the benefit of avoiding these premature mortalities as ranging from $153 to $233 million per year.

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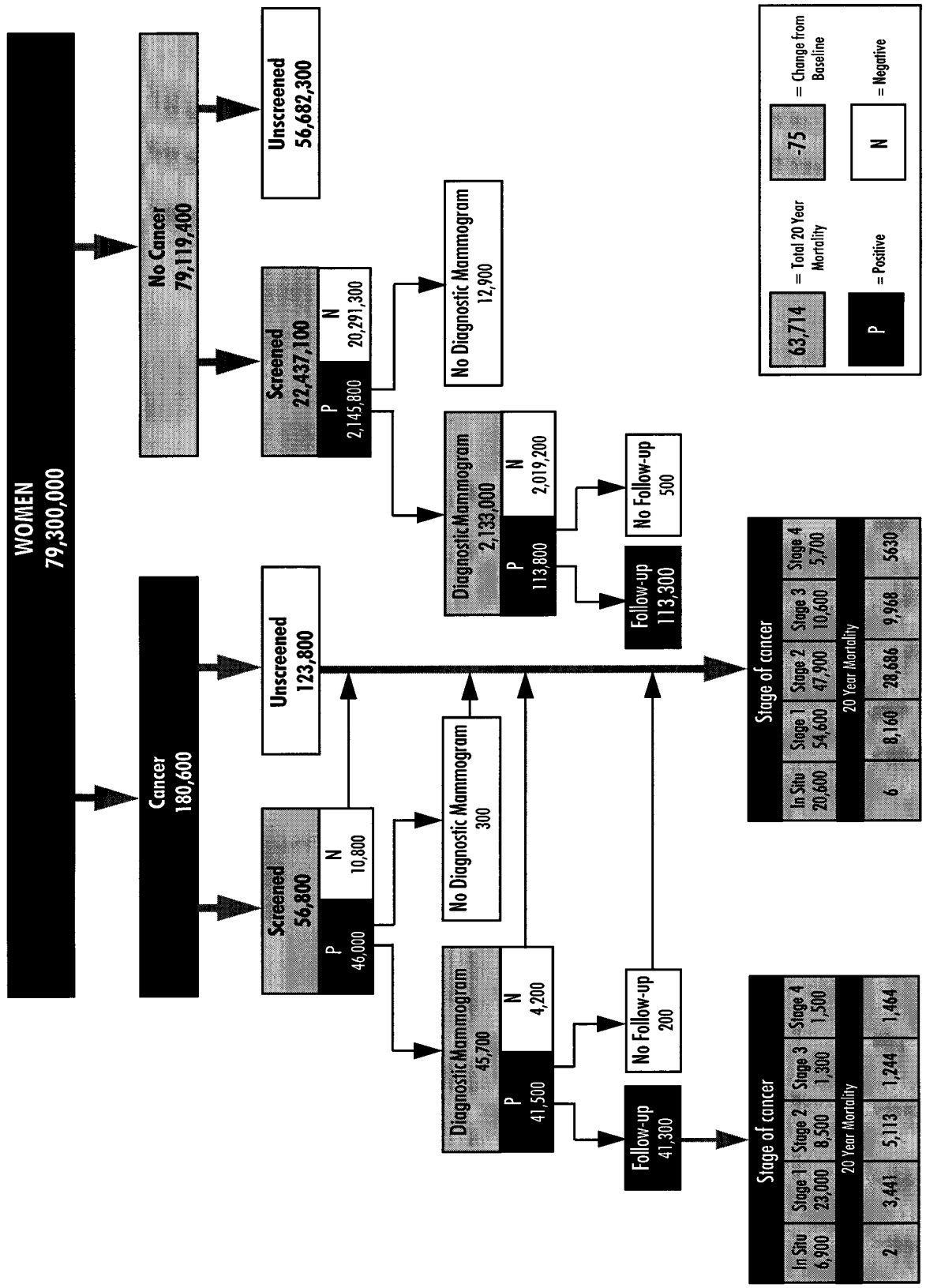


**Note: Totals may not add due to rounding**

**Figure 2. Model with 5-percent quality improvement, and final rule compliance costs.**

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A 5 percent quality improvement would also decrease cancer treatment costs by about $1.9 million. In addition, the reduction in false positives would produce less anxiety and stress valued at $12.7 million, and reduced diagnostic costs of $14.5 million. In total, quality improvements of 5 percent would generate annual benefits of from $182 to $263 million, far exceeding the expected annual compliance costs of $38.2 million. From a cost-effectiveness perspective, the cost per QALY would amount to about $20,000. Even if the overall quality improvement were only 2 percent, the estimated annual benefits of the final regulation exceed the estimated annual compliance costs.

*C. Small Business Impact*

According to the Small Business Administration, any doctor's office, clinic, or hospital with $5 million or less in revenue is considered small. In addition, any not-for-profit enterprise that is independently owned and operated and not dominant in its field is considered small. On this basis, mammography is offered in about 4,800 small doctor's offices or clinics and 5,000 small hospitals, comprising up to 98 percent of all mammography facilities.

FDA recognizes that the nature of these regulations may have a disproportionate effect on very small volume mammography facilities, as fixed costs of compliance for equipment improvements are likely to increase the cost per mammogram for low volume facilities relatively more than for high volume facilities. The cost of a mammogram is expected to increase by 3.4 percent in an average facility and by 4.2 percent in the smallest 10 percent of facilities. However, total revenues are also likely to increase. Overall, the annual net revenues attributable to mammography (gross revenues minus gross costs) are estimated to decline by approximately $1,000 in the smallest 10 percent of facilities, whereas the larger facilities may experience net revenue gains. ERG judged that these smallest facilities would have an increased vulnerability for closure. These results are fully described in the agency's final Economic Impact Analysis.

FDA also examined the effect on small businesses of alternative implementation schedules for this proposal. For example, one alternative would have required an even more elaborate equipment upgrade, effective immediately upon issuance of the regulations. The agency rejected this alternative becauseit would have placed an unnecessary burden on the industry, costing more than $120 million annually. By eliminating some specifications that were marginal to ensuring mammography quality, and phasing in certain requirements to allow for normal replacement of current equipment, the agency substantially reduced the cost of compliance. FDA also considered postponing the implementation of the final equipment requirements by an additional year. This alternative would have reduced the annual compliance costs by $7.1 million, but delay the impact on quality improvements. The final implementation schedule was selected as a reasonable balance between compliance costs and quality improvements. FDA also considered providing an exemption for small facilities in shortage areas, but concluded that the importance of mammography quality made this tradeoff unacceptable, and that a primary objective of MQSA was to ensure quality for all patients. The agency's final Economic Impact Analysis includes a discussion of several additional alternatives.

*D. Total Impact of the MQSA*

The total compliance costs for all of the regulations implementing the MQSA are the sum of the costs for the interim rules already in place, as well as for the final regulations as estimated above. Thus, to assess the total costs of the MQSA, FDA also estimated the costs of complying with the interim regulations.

Interim regulations implementing the MQSA required facilities to be accredited by an FDA-approved body as a first step towards receiving a certificate. FDA approved the ACR and the States of Iowa, Arkansas, and California to accredit facilities. The standards used by these bodies to accredit facilities were developed by FDA, but are largely based on the standards previously used by the ACR in their voluntary accreditation program. Because the ACR was the only national accreditation body and had already accredited approximately half of the mammography facilities in the country in its voluntary program, the majority of unaccredited facilities applied to the ACR for accreditation in order to continue to provide mammography services. On being notified by the ACR or one of the State bodies that a facility was accredited, FDA issued a certificate to the facility.

Approximately 5,500 facilities had not fully completed the accreditation and certification process by October 1, 1994 and approximately 1,000 accredited facilities were assumed to incur low levels of compliance cost. FDA estimated the costs of compliance with the interim rule by dividing these 6,500 facilities (5,500 unaccredited and 1,000 accredited) into groups with low, moderate, and high levels of noncompliance. Approximately 4,500 of these facilities had completed the accreditation and certification process by the end of the 6-month period of the provisional certificates or required minor improvements to achieve accreditation. These facilities were assumed to have low levels on noncompliance. Approximately 1,500 were able to complete the accreditation and certification process by the end of a 90-day extension of their 6-month provisional certificate. These facilities were assumed to have a moderate level of noncompliance. The remaining approximately 500 facilities were assumed to have a high level of noncompliance.

Discussions with expert consultants and operators of mammography facilities indicated that a low level of noncompliance would typically include minor recordkeeping and personnel training deficiencies. A moderate noncompliance level would typically include (beyond the low level) some quality assurance deficiencies and equipment requiring retrofit. Finally, facilities with high levels of noncompliance would incur costs for replacement of a mammography unit (in addition to ''moderate'' costs less retrofit). Based on this methodology, FDA estimates the annual costs of the interim rule at about $23.4 million. Adding the additional $38.2 million cost attributable to the final rules indicates that the total annual compliance costs of the MQSA are about $61.6 million.

The benefits of the interim rules result from their impact on mammography quality. A poll of industry experts indicated that the interim rules may have improved mammography quality by between 2 and 10 percent. Other reports have estimated that based on 1992 levels of quality, typical community quality levels may have been as much as 13 percent below the quality levels found in academic or research centers. FDA agrees that post-interim levels of quality may be approximately 10 percent lower than those found in typical academic settings, which implies a relative quality gain of 3 percent due to the interim regulations. FDA also found that, given average annual compliance costs of $23.4 million for the interim regulations, a 3.1 percent quality improvement would account for the current level of mammography use (all else being equal). Thus, FDA estimates that the interim regulations have

resulted in an approximate 3 percent increase in mammography quality. With this assumption, FDA's impact model calculates that the overall annual benefits of the interim rule range from $108 to $155 million, including the annual gain of about 44 lives and 242 discounted QALY's.

*E. Conclusions*

In summary, the final regulations will generate mammography quality increases above those already achieved by the interim regulations. As shown in the summary table, the annual costs of compliance with these final regulations are estimated at $38.2 million. Expected benefits will accrue as a result of fewer breast cancer fatalities due to the earlier detection of lesions and the avoidance of unnecessary surgery. While the magnitude of the expected quality increases are uncertain, an improvement of 5 percent in mammography sensitivity and specificity would result in annual benefits valued at from $178 to $257 million. With respect to all of the MQSA requirements, the annual compliance costs of the combined interim and final regulations equal about $61.5 million, and the annual benefits (assuming total quality increases of 8 percent) range from $284 to $408 million.

TABLE 1.—SUMMARY OF ECONOMIC IMPACTS (MILLION $)

| | Interim Rule[1] | Final Rule[2] | Total[3] |
|---|---|---|---|
| Compliance Costs | 23.4 | 38.2 | 61.6 |
| Benefits | 108.2–153.8 | 181.7–262.7 | 289.9–416.5 |
| Diagnostic Cost Decreases | 9.0 | 14.5 | 23.5 |
| Treatment Cost Decreases | 1.1 | 1.9 | 3.0 |
| Anxiety Cost Decreases | 7.8 | 12.7 | 20.5 |
| Value of Lives Extended | 90.3–135.9 | 152.6–233.6 | 242.9–369.5 |

[1]Assumes 3 percent increase in mammography quality
[2]Assumes 5 percent increase in mammography quality
[3]Assumes 8 percent increase in mammography quality

*F. Responses to Comments on the Impact Analysis of the Proposed Regulation*

1. Cost Analysis

FDA published a preliminary impact analysis in association with the final regulations on April 3, 1996. Public comments were invited on the methodology and projections included in that analysis.

One comment disagreed with the cost-benefit analysis and stated that the imposition of additional costs would adversely affect public health because fewer women will be able to receive the benefits of mammography.

FDA agrees that additional costs with no concurrent quality improvement may adversely affect mammography access. FDA also recognizes that access without quality is of no public benefit. FDA believes, however, that the assurance of quality resulting from these regulations will overcome any possible negative impacts. This belief is supported by a CDC study on mammography utilization that showed a continued increase in screening mammography examinations under the MQSA interim rules (Ref. 4).

One comment stated that most CEU classes for technologists cost between $75.00 and $100.00 for 6 to 8 credits, and require additional travel expenses. FDA agrees with the estimate provided by this comment. FDA estimated that the cost per hour of technologist's CEU would cost approximately $16.00 per credit hour and used this estimate in its impact analysis. This estimate was based on input from consultants and is within the range presented by this comment.

Numerous comments stated that the **Federal Register** notice for the proposed rule lacked sufficient methodological detail and should have included the cost of each requirement and the per facility or per procedure cost.

FDA agrees that the summary of impacts included in the **Federal Register** did not include detailed methodologies, discussions of assumptions, and sources of data. Nevertheless, as is required, FDA had provided a clear explanation of the calculations used for the cost/benefit analysis in the Full Regulatory Impact Analysis which was available for review at the Dockets Management Branch. Similarly, the agency's final Economic Impact Analysis, which provides substantial detail on the cost estimates is available at the same location that document can also be retrieved from FDA's home page on the World Wide Web (www.fda.gov).

A number of comments asserted that the equipment requirements would mandate the replacement of most mammography units and would increase the cost of these replacement units and that these costs were underestimated by FDA. One comment calculated the cost of replacing 15,000 mammography units, priced at $70,000, at more than $1 billion. The comment also calculated the cost of replacing 5,000 processors (½ of total), priced at $15,000, at $75 million.

FDA disagrees with the assumption that all mammography units in the country (which actually number about 12,000 instead of 15,000) or even most units will have to be replaced in order to meet the final rules. The Economic Impact Analysis that accompanies this final rule includes a detailed discussion on the estimation of the replacement costs. FDA has estimated the costs of the equipment requirements of the proposed rule by estimating replacement and retrofit costs through contacts with mammography equipment manufacturers. For replacements, the analysis considers the lost useful life of the machine. FDA also solicited input on compliance costs from mammography unit manufacturers and project consultants. These manufacturers indicated that not all mammography units would require replacement or retrofit and that prices for the new units would be identical to current prices. Based upon these sources of information, FDA estimated the total costs related to the equipment requirements of the proposed regulations to be approximately $270 million or $35 million in average annual costs (over the 10-year analysis period at a 7 percent discount rate). The agency notes that, after consideration of the public comments and other information, a number of equipment requirements, including those related to processors, were deleted before these regulations were issued. The impact of those deletions was to reduce the total estimated expenditure of meeting the equipment requirements in lost resources to $241 million and the average annual costs over the 10-year analysis period to $28.5 million.

One comment stated that phasing in equipment requirements 5 and 10 years after the effective date of the regulations would significantly increase costs if facilities are required to replace the unit in 5 years and then again in 10 years.

FDA believes that this comment stems from a misinterpretation of the proposal. FDA did not expect facilities to replace units every 5 years. Input on the equipment requirements from manufacturers indicated units would be available almost immediately after the regulations were published that would be able to meet the 5- and 10-year requirements. Thus, if a unit had to be replaced to meet an immediate requirement, a new unit could be selected that would meet the 5- and 10-year requirements as well. The facility would not need to purchase additional replacement units ''every 5 years.'' FDA's purpose in phasing in some requirements 5 and 10 years in the future was to provide time for facilities whose units met the immediate requirements but not the 5- or 10-year requirements to replace those units on their regular replacement schedule. This would decrease the burden by allowing machines to be replaced as they reach the end of their useful life. However, for reasons discussed in the responses to the comments on the equipment requirements, most of the 5-year requirements and all of the 10-year requirements were removed before these final regulations were issued.

Two comments expressed concern that the cost requirements for training every technologist to perform weekly or daily phantom checks were not considered in the impact analysis of the proposed regulations. Another comment estimated that the cost of performing the daily phantom tests for 240 days per year at $0.80 per sheet of film would be an additional $192.00 per unit. Using the estimated 10,800 certified units this would mean an additional cost of $2,073,600 per year.

FDA notes that the weekly phantom tests are identical to those currently being performed monthly under the interim regulations. No additional training costs will be incurred beyond those already included in the cost estimates of the interim regulations. FDA did not include any cost requirements for training to perform the daily phantom checks or for performance of the test because the agency did not propose such a test but merely requested public comment on its possible value. As previously discussed, FDA concluded from the public comments that further studies would be needed to confirm the value of such a test before it was made a regulatory requirement. Because it was not made a regulatory requirement, no costs either for training in its performance or performing the test needed to be included in these cost estimates.

A number of comments stated that FDA underestimated costs by not considering all of the factors that will contribute to increased provider and consumer cost.

FDA's Economic Impact Analysis has attempted to consider all of the factors that will contribute to increased costs from compliance with the final rule. This analysis is available through the Dockets Management Office, as well as the World Wide Web. As these comments did not identify the factors believed to have been overlooked, the agency is unable to give a more specific response.

Numerous comments asserted that the cost of lay notification would significantly increase the costs of mammography. These comments estimated that the cost ranged from $0.78 to $15.00 per notification.

For the proposed rule, FDA used a methodology to estimate the cost of patient notification that is similar to that described in the comments. The Economic Impact Analysis presented an estimate of $0.94 per written notification including 2.5 minutes of an office staff worker's time and cost of postage. However, this proposed requirement was removed from the final rule before it was codified, so these estimated costs will not occur.

A number of comments stated that the increased costs to comply with the final rule will result in facility closings (especially for small-volume facilities and rural facilities) and loss of access. One comment also stated that FDA has not adequately justified the cost of the regulation in the face of reducing access to low income populations.

FDA agrees that it is possible that increased costs of conducting mammography due to these regulations may cause some facilities to close if those facilities are currently not offering high quality mammography. However, FDA disagrees that such an impact has not been adequately explored. FDA has attempted to identify areas of potential access problems and believes that very few patients would be adversely affected if, as is anticipated, few, if any, facilities close as a result of the burdens of the final regulations. When facilities do close, alternate facilities are usually expected to be available within a reasonable distance. The agency also notes that the GAO study cited earlier found that the interim regulations, which had a similar cost impact, had little impact on access. FDA agrees that access for low income women is a potential problem, but does not believe that these regulations will greatly increase this problem. Nevertheless, FDA will monitor this potential outcome to ensure that any adverse impact on underserved populations is minimized.

One comment stated that costs were underestimated because only the incremental costs of nonvoluntary compliance were identified.

FDA disagrees with this comment. The quality standards contained in these regulations reflect standards of good practice, so it would not be surprising to find that many facilities were already complying with them before the regulations went into effect. Where voluntary compliance with regulatory requirements existed prior to implementation of the rule, costs were not included in the agency's Economic Impact Analysis because they are due to the facility's own desire to achieve quality mammography and not to the regulations. FDA agrees that if compliance costs occur only as a result of or in anticipation of a regulation and would be discontinued in its absence, such costs should be considered. However, FDA believes that most mammography facilities did not anticipate the specific regulatory requirements of this rule, and so any past actions to improve quality at their facilities were independent actions on their part.

Several comments noted that the proposal included only costs associated with the proposed regulations and not the interim rule. They stated that the costs and benefits of the entire MQSA should be estimated.

FDA agrees with these comments and has included estimates of the interim impacts for these final regulations.

One comment noted that costs may be understated because FDA assumed the lowest compliance cost. This comment stated that because some facilities would incur higher costs, the overall costs were underestimated.

FDA disagrees with this comment. The agency assumed that each facility would adopt a least-cost compliance strategy, which is standard economic methodology for analysis of regulations as required by Executive Order 12866. While some facilities would have higher costs, other facilities would have lower (or no) costs. Thus, the least-cost method of compliance for the average facility is a reasonable method of estimating industry wide costs. It is possible that this comment misunderstood the methodology used to estimate costs.

One comment stated that FDA has not adequately accounted for decreases in mammography usage due to expected cost increases.

FDA has attempted to address this issue for the final regulations. FDA agrees that cost increases are likely to decrease mammography use, all else being equal, but that perceived increases in mammography quality are likely to offset any negative impact. This issue is discussed above in B.2 and in the Economic Impact Analysis that accompanies the final rule.

One comment asserted that FDA's costs were ''unrealistic,'' rely only on consultant opinion and are, therefore, unreliable.

FDA disagrees with this comment. Cost estimates were derived from an extensive process of site-visits and expert input and no alternative data were included with this comment. The agency's cost methodology is fully detailed in the Economic Impact Analysis.

Several comments noted that specific activities were underestimated. FDA cannot respond to these comments because no supporting data were supplied.

2. Benefits Analysis

A number of comments maintained that FDA overstated the expected improvement in avoiding cancer deaths from the final regulation and that the benefit estimates should be based on scientific literature.

FDA believes that quality improvements in mammography will result in health gains, of which reductions in breast cancer mortality are a major contributor. FDA has attempted to assess the potential quality gains from the requirement of the final rule by reviewing relevant literature and through contact with experts in mammography quality. The Economic Impact Analysis that accompanied the proposed regulations included a detailed and referenced description of the benefits estimate. Similarly, the analysis of impacts for the final regulations include, a comprehensive description of the methodology.

One comment maintained that the final rule was a waste of money because the ACR program has already accomplished a goal of ''reasonably achievable mammographic quality.''

FDA disagrees with this comment. While voluntary accreditation by ACR did much to improve quality in participating facilities, the agency notes that, at the time of passage of the MQSA, less than half of the mammography facilities in the country had sought voluntary accreditation. The MQSA and its implementing regulations have led to the establishment of a uniform minimum set of quality standards to be met by all mammography facilities, including standards in areas not previously covered by the ACR program, and have provided increased assurance that these standards continue to be met between the times of accreditation. As shown in the above impact analysis, the agency believes that the benefits achieved more than compensate for the additional costs.

One comment stated that there has been a significant improvement in the quality of mammography performed under the interim regulations and further maintained that this quality improvement will continue under the final regulations.

FDA agrees with this comment. Quality improvements attributable to the interim regulations are estimated in conjunction with those attributable to the final regulations.

Several comments stated that because sensitivity is defined as the number of true positives divided by the number of true positives plus false negatives, a gain in sensitivity rate would have no effect on the false positive rate.

FDA agrees with these comments. FDA believes that both false negatives and false positives would be reduced by the quality improvements expected from these regulations. Thus, FDA believes that expected quality improvements would be likely to improve both sensitivity and specificity of screening mammography examinations. FDA notes that a typographical error in the analysis of impacts accompanying the proposed regulations may have contributed to these comments.

One comment stated that the discussion on sensitivity confuses the notion that there are inherent tradeoffs between sensitivity and specificity with the mathematical reality that this is not necessarily the case. The respondent believed also that this error may be due to confusing sensitivity with PPV.

FDA recognizes that the sensitivity and the PPV of a diagnostic test are not identical. Nonetheless, FDA believes that sensitivity and specificity provide reasonable quality measures for evaluating these final regulations.

Several comments stated that there is an error in the benefits analysis where it states, ''a five percent gain in sensitivity measurements of 80 percent would indicate a revised sensitivity level of 81 percent (a reduction of the rate of false positives from 20 to 19 percent).'' The comments stated that 5 percent gain to 80 is 84 not 81.

FDA agrees that the description of the impact was not well stated. A 5 percent quality improvement is defined in FDA's analysis as a 5 percent reduction in inaccurate testing results. Thus, if 20 percent of the diseased, screened population are currently not identified, a 5 percent quality improvement would see 19 percent not identified. The 5 percent is actually a 5 percent reduction in the complement of sensitivity.

Numerous comments asserted that the estimated willingness to pay to avoid a statistical loss of life of $5 million was too high and was unsupported.

FDA disagrees with these comments. For illustrative purposes, FDA has quantified the decreased breast cancer mortality potentially resulting from the rule using an average value of $5.0 million per each avoided death. This value is the implied value of society's willingness to pay to avoid the likelihood of an additional death as derived from economic literature, as referenced in the full Economic Impact Analysis. The methodology used to estimate this value is based on wage-premiums necessary to induce workers to accept riskier occupations and is a commonly used approach for estimating the value that society appears to be willing to pay to avoid a statistical death.

Several comments questioned the probability of expected benefits accruing from improvements in specificity. The comments identified this as the area where the greatest cost savings could be realized, and underlined this area as one which should be a target for improvement by the MQSA. Relatively small improvements in specificity could markedly reduce the numbers of false positive results nationwide, resulting in less diagnostic testing.

FDA agrees with these comments. These cost savings were addressed for the proposed regulations and are addressed for these final regulations.

One comment stated that raising the sensitivity of a test results in an increase in the false positives rather than a decrease.

FDA disagrees. The agency finds that quality improvements made to comply with the final rule are likely to improve sensitivity and/or specificity by raising the typical community receiver operating characteristic curve toward the optimum level. That is, quality improvements due to these regulations would change the entire relationship between sensitivity and specificity by improving the production function of mammography. As a result, both measures would be improved by these regulations.

One comment questioned the use of identified cancer stages used in the benefit analysis and noted that there is controversy associated with the impact of ductal carcinoma in situ on health outcomes.

FDA agrees with this comment and adjusted the benefit analysis for the final regulations.

One comment asserted that benefits were overstated because the general trend in mammography was toward higher quality even in the absence of the regulations.

FDA disagrees that the beneficial impact of these regulations has been overstated. Current trends in mammography quality are accounted for in baseline conditions.

Several comments noted areas of potential benefit that were not accounted for in the analysis that accompanied the proposal. These areas include the benefit of increased assurance to patients, the benefits of increased diagnostic quality, and reductions in treatment costs for identified cancers.

FDA agrees with these comments and has included these categories in this final analysis.

One comment stated that references for the benefit analysis were not available. FDA notes that references were included with the Economic Impact Analysis that accompanied the proposed regulations.

One comment noted that the affected population would change over time and that FDA has assumed a static population.

FDA agrees with this comment. FDA notes, however, that forecasting changes in future populations would likely increase the expected benefits because of the age distribution changes expected as the baby boom generation moves into ages of greater risk from breast cancer.

Several comments questioned the assumptions used in FDA's benefit estimation model.

FDA agrees that several of the key assumptions are uncertain. Nevertheless, the agency believes that the absence of scientific certainty does not preclude the development of preamble projections based on reasonably supported amplifying assumptions. The Economic Impact Analysis for these final rules provides sensitivity analyses that demonstrate the effects of modifying a number of these variables.

## VI. Paperwork Reduction Act of 1995

### *A. Information Collection Provisions in the Final Rule*

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The following title, description, and respondent description of the information collection provisions are shown with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

*Title*: Reporting and Recordkeeping Requirements for Mammography Facilities.

*Description*: The final rule collects information from accrediting bodies and mammography facilities. Under the final rule, each accreditation body is required to submit applications and establish a quality assurance program. Each mammography facility is required to establish and maintain a medical reporting and recordkeeping system, a medical outcomes audit program, a consumer complaint mechanism, and records documenting personnel qualifications.

These information collection requirements apply to accreditation bodies and to mammography facilities. In order to be an approved accreditation body, private nonprofit organizations or State agencies must submit an application to FDA and establish procedures and a quality assurance program. Mammography facilities must obtain and prominently display an FDA-issued certificate or provisional certificate; have a medical reporting and recordkeeping program, a medical outcomes audit program, and a consumer complaint mechanism; and maintain records documenting personnel qualifications. These actions are being taken to ensure safe, accurate, and reliable mammography on a nationwide basis.

*Respondent Description*: Businesses and other for-profit organizations, nonprofit organizations, Federal, State, and local governments.

FDA estimates the burden of this collection of information as follows:

**Requirements for Accreditation Bodies of Mammography Facilities and Quality Standards and Certification Requirements for Mammography Facilities; General Facility Requirements**

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours | Total Capital Costs | Total Operating & Maintenance Costs |
|---|---|---|---|---|---|---|---|
| 900.3 | 6 | 1 | 6 | 60 | 360 | | |
| 900.3(b)(3) | 10 | 1 | 10 | 60 | 600 | $50 | |
| 900.3(c) | 4 | 0.14 | 0.56 | 15 | 8.4 | | |
| 900.3(e) | 1 | 0.2 | 0.2 | 1 | 0.2 | | |
| 900.3(f)(2) | 1 | 0.2 | 0.2 | 200 | 40 | | |
| 900.4(c) and (d)[1] | 834 | 1 | 834 | 1 | 834 | | |
| 900.4(e)[2] | 10,000 | 1 | 10,000 | 8 | 80,000 | | |
| 900.4(f)[3] | 1,000 | 1 | 1,000 | 14.5 | 14,500 | | |
| 900.4(h)[4] | 6 | 1 | 750 | 6 | 4,500 | | |
| 900.4(i)(2) | 1 | 1 | 1 | 1 | 1 | | |
| 900.6(c)(1) | 1 | 1 | 1 | 1 | 1 | | |
| 900.11(b)(2) | 25 | 1 | 25 | 2 | 50 | | |
| 900.11(b)(3) | 5 | 1 | 5 | .5 | 2.5 | | |
| 900.11(c) | 10,000 | 0.0050 | 50 | 20 | 1,000 | | $1,000 |
| 900.12(c)(2) | 100 | 1 | 100 | 5 | 500 | | |
| 900.12(j)(1) | 10 | 1 | 10 | 1 | 10 | | |
| 900.12(j)(2) | 1 | 1 | 1 | 50 | 50 | | |
| 900.15(d)(3)(ii) | 10,000 | 0.0020 | 20 | 2 | 40 | | $100 |
| 900.18(c) | 10,000 | 0.0005 | 6 | 2 | 12 | | $60 |

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN—Continued

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours | Total Capital Costs | Total Operating & Maintenance Costs |
|---|---|---|---|---|---|---|---|
| 900.18(e) | 10 | 0.1000 | 1 | 1 | 1 | | $10 |
| TOTAL | | | | | 102,510 | $50 | $1,170 |

[1]Formerly § 900.4(b) under the interim rule.
[2]Formerly § 900.4(d) under the interim rule.
[3]Formerly § 900.4(e) under the interim rule.
[4]Formerly § 900.4(g) under the interim rule.

**Requirements for Accreditation Bodies of Mammography Facilities and Quality Standards and Certification Requirements for Mammography Facility Requirements; General Facility Requirements and Personnel Requirements**

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours | Total Operating & Maintenance Costs |
|---|---|---|---|---|---|---|
| 900.3(f)(1) | 10 | 130 | 1,300 | 200 | 2,000 | |
| 900.4(g)[1] | 10,000 | 1 | 10,000 | 1 | 10,000 | |
| 900.11(b)(1)[2] | 1,000 | 1 | 1,000 | 1 | 1,000 | |
| 900.12(c)(4)[3] | 10,000 | 1 | 10,000 | 1 | 10,000 | |
| 900.12(e)(13) | 6,000 | 52 | 312,000 | 0.125 | 39,000 | |
| 900.12(f) | 10,000 | 1 | 10,000 | 1 | 10,000 | |
| 900.12(h) | 10,000 | 2 | 20,000 | 0.5 | 10,000 | $20,000 |
| TOTAL | | | | | 82,000 | $20,000 |

[1]Formerly § 900.4(f) under the interim rule.
[2]Formerly § 900.11(c)(1) under the interim rule.
[3]Formerly § 900.12(e)(1) under the interim rule.

Most of this burden is not new, but rather results from requirements continued from the interim rule. FDA estimated the annual burden for reporting and recordkeeping requirements under the interim rule to be 120,944 hours (58 FR 67562 and 67569). The additional requirements contained in these final rules will add 63,566 burden hours to this estimate, resulting in an estimated total annual burden of 184,510 hours.

The burden estimate for this final rule differs from the proposed rule in several respects (see 61 FR 14865 to 14868). First, FDA revised § 900.12(c)(2), which proposed written notification of examination results to all mammography patients. The final rule requires that each facility maintain a system to ensure that the results of each mammographic examination are communicated to the patient in a timely manner. This revision resulted in the removal of proposed § 900.12(c)(2)(i) from the paperwork burden estimates. Second, FDA revised § 900.12(d)(2), which proposed the specific documentation to be maintained by each facility as part of its quality assurance program. This revision included removing §§ 900.12(d)(2)(i), 900.12(d)(2)(ii) and 900.12(d)(2)(iii) from the final rule and combining §§ 900.12(d)(2) and 900.12(d)(2)(iv) from the proposed rule into § 900.12(d)(2) for the final rule. This revision is reflected in these estimates of the recordkeeping burden. Third, FDA added several reporting and recordkeeping burden estimates that are not new to the final rule, but whose impact was overlooked in the burden estimate for the proposed rule. Also, FDA renumbered some of the provisions for the final rule, due to removal or additions of other provisions; these revisions had no effect on the paperwork burden estimates. The following sections concerning paperwork burden were renumbered: § 900.4(a)(7) in the proposed rule is § 900.4(a)(6) in the final rule, and §§ 900.12(f)(2) and 900.12(f)(4) in the proposed rule are §§ 900.12(f)(1) and 900.12(f)(3) in the final rule, respectively.

*B. Comments on the Paperwork Reduction Act Statement*

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act, FDA provided an opportunity for public comment on the information collection provisions of the proposed rule (April 3, 1996). A small number of comments addressed FDA's Paperwork Reduction Act statement. In general, these comments asserted that FDA had underestimated burden or had not considered all of the reporting and recordkeeping requirements.

One comment stated that FDA's Paperwork Reduction Act statement underestimated the time burden on mammography facilities for recordkeeping and reporting. The comment further stated that FDA's estimate of 23,553 hours, which translated into less than 2.5 hours per facility (based on an estimated 10,000 mammography facilities in the United States), was low. The comment asserted that FDA underestimated or ignored the incremental burden on facilities from the interim rule to the final rule. The comment further stated that at least one person at each mammography facility

must understand the final rule. The author of the comment estimated this task at 10 hours per person at each of the estimated 10,000 mammography facilities.

FDA disagrees with this statement in general, but upon review of the burden estimates under the proposed rule FDA has revised some of the time estimates. For example, FDA has added hours to cover § 900.12(e)(3)(13), infection control, because its burden was overlooked under the paperwork burden analysis of the proposed rule.

FDA also agrees that someone in the mammography facility will have to understand the final rule and that it will take some time to develop this understanding. The agency believes, however, that the time estimate suggested by the comment is far too high. This belief is based upon three considerations. First, the basic framework of the requirements has not significantly changed from the interim rule. Many of the additional details in the final rule are taken from policies developed under the interim rule, with which the facilities are already familiar. Because of this overlap, the time required to understand the final rule is less than it would be if they were entirely new. Second, the recordkeeping and reporting burdens are estimated on an annual basis; therefore, each estimate is stated as an average time per year. Whatever burden there would be in understanding the new regulations would be primarily a one-time burden. If an individual spends x hours the first year developing an understanding of the regulations, the time required in the second and subsequent years will be much less than x because the person will already be familiar with them. The average time per year for understanding the regulations thus would be only a small fraction of x. Third, in compliance with the Paperwork Reduction Act, it is the time burden for reporting and recordkeeping that is being estimated. Thus, only the time required to understand the new reporting and recordkeeping requirements, not to understand the total requirements, would properly be included in these estimates. The combined effect of these three factors, the agency believes, reduces the time burden for understanding the requirements that should be included in these estimates significantly. The burden for understanding each requirement has been included in the individual burden estimates for that requirement.

One comment stated that FDA had not estimated any burden for compliance with proposed § 900.12(f), which requires each facility to implement a medical outcomes audit. The author of the comment estimated that the burden of such a requirement would require at least 10 hours of an interpreting physician's time at each of the estimated 10,000 mammography facilities. Several other comments also stated that proposed § 900.12(f) was an undue burden on freestanding facilities. The comments discussed the difficulty in tracking down and obtaining all biopsy and consultation outcomes. One comment noted the lack of evidence that outcome measurement contributes to improved care.

FDA understands the difficulty with tracking outcomes data but such data are critical in assessing the quality of mammography at facilities. FDA also notes that most of the requirements in § 900.12(f) do not require any additional reporting or recordkeeping burden beyond what was required under the interim rule.

One comment also asserted that FDA had failed to include the time burden for proposed § 900.12(g), which adds requirements for mammography of patients with breast implants. The comment stated that FDA should have estimated the time burden related to scheduling patients with implants, documenting patients with implants, and requiring the presence of an appropriately trained interpreting physician onsite during mammography of women with implants. The author of the comment estimated that the above would require an additional 10 to 20 hours of reporting and recordkeeping at each mammography facility.

As discussed previously, FDA has changed the proposed requirement that each facility should inquire whether a patient has an implant at the time of scheduling to a requirement in the final rule that each facility shall inquire as to whether the woman has an implant prior to the examination. The final rule also eliminated the requirement that an interpreting physician be present. Even under the proposal, the additional recordkeeping time would have been minimal and the revision in the final rule gives the facility flexibility in determining when and how the information is collected for the patient's record. All facilities maintain patient records with information such as address, telephone number, insurance information, and medical history. The additional time to ask a yes or no question on implants and record the answer is negligible.

Another comment stated that FDA had failed to estimate the additional requirements and documentation associated with personnel requirements in proposed § 900.12(a). The comment estimated that additional documentation requirements would necessitate at least 5 hours of additional time for approximately 1,000 medical physicists, and approximately ¼ hour for each mammography facility.

FDA acknowledges that § 900.12(a) contains some increases in the required level of personnel training and experience from the interim rule. However, FDA did not include any recordkeeping burden estimates for the personnel requirements under either the interim or final rules because the agency believes that it is usual and customary practice for mammography facilities to keep records of the qualifications of their employees.

Although this position makes moot the question of the amount of time required for recordkeeping related to these requirements, FDA would like to note that there are factors that the author of the comment may not have been aware of that make the estimates in the comment excessive. Most changes in the personnel qualifications are only increases in the amounts of the interim requirements. In such cases there is no additional recordkeeping burden. It requires no more effort, for example, under the final rule, to keep a letter in a doctor's records indicating that he or she had 3 months of training in mammography during residency that it did, under the interim rule, to keep a letter indicating he or she had 2 months of such training.

For most of the new personnel requirements in the final rule, such as the continuing experience requirements for technologists and physicists, the information that bears on whether these requirements are met often already exists in the form of various work records. All that is needed is to place a copy or summary in each person's file.

The remaining new standard establishes an initial requirement of a minimum level of education and training for medical physicists. FDA believes that the majority of physicists providing services to mammography facilities will have exceeded this level in meeting the requirement that the medical physicist be board-certified, State licensed, or State approved, which was retained from the interim rule. In such cases, the agency intends to minimize the burden by accepting the documentation of board approval, State licensure, or State approval (in States whose standards for approval exceed the minimum level) as adequate evidence that the second requirement is also met.

Physicists approved by States that require a level of qualification for approval lower than that in the second

requirement will have to provide additional documentation but the time required is likely to be significantly less than the 5 hours estimated in the comment. More importantly, as this is an initial requirement, it will be a one time burden. To be compared with the other burden estimates, it must be averaged over the physicists's entire career, which could be 30 years or longer.

Again, because keeping records of personnel qualifications is usual and customary practice, FDA has not included this in the burden estimates. The agency notes, however, for the reasons discussed above, that the comment greatly overestimates the time required for the new recordkeeping.

One comment stated that virtually all of the requirements in the proposed rule duplicate requirements of accreditation bodies and noted that FDA inspectors require much of the same personnel documentation required by the ACR.

FDA notes that the author of the comment has misunderstood the nature of the accreditation system required under the MQSA. The requirements of the FDA-approved accreditation bodies are not established by those bodies but rather are FDA-established quality standards that the accreditation bodies, as a condition of their approval, must ensure are met by the facilities they accredit. Thus, there is only one set of requirements, not two or more duplicate sets, and the actions identified in the comment are mandated by the legislation in order to increase the likelihood that quality mammography will be consistently achieved.

Several comments asserted that the proposed rule would create an unnecessary amount of paperwork that would ultimately take away from time with patients. One comment asserted that the reporting requirements would necessitate a computer system and additional clerical support.

FDA has attempted to limit the paperwork burden to only those recordkeeping and reporting requirements necessary to ensure that facilities meet minimum quality standards. As discussed above, FDA has also reduced the paperwork burden of the final rule by removing several reporting and recordkeeping requirements from the final rule. The agency believes that the paperwork impact, as estimated in Tables 1 and 2, is not unreasonable in view of the benefits to be gained from the quality standards that made the recordkeeping and reporting necessary.

A number of comments asserted that proposed § 900.12(c)(2), which would have required written notification of mammographic examination results to all mammography patients, would cost time and postage expenses and would generate much paperwork. Some comments asserted that this practice would be redundant for patients with referring physicians who could explain the results.

FDA has revised § 900.12(c)(2) to require that each facility shall maintain a system to ensure that the results of each mammographic examination are communicated to the patient in a timely manner. FDA has allowed for increased flexibility in the notification of patients by allowing written or other notification by either the mammography facility or the referring physician. FDA believes that some form of patient notification is a standard of good practice that is currently followed voluntarily by virtually all mammography facilities, so the burden of this requirement will fall only on those few facilities who are not currently meeting such a standard. The flexibility of notification method allowed under the revision of § 900.12(c)(2) will make the burden minimal even for these facilities.

Several comments asserted that proposed § 900.12(h), which requires the development of a consumer complaint mechanism, was unnecessary. The comments stated that all complaints should be handled on an individual basis at each facility according to the protocol of that facility. One comment asserted that the proposed rule would be very costly in terms of staff time and materials.

This comment has misinterpreted the requirements of § 900.12(h), which gives facilities the flexibility to develop their own consumer complaint mechanism in the manner they feel most appropriate. The requirement that each facility must maintain records of each serious complaint over the last 3 years should be of minimal burden to facilities and would only necessitate a file including the appropriate correspondence by the complainant, facility, and accrediting body. Many facilities already have some form of consumer complaint mechanism and would not incur significant additional burden by meeting the requirements of the final rule.

One comment agreed with proposed § 900.12(c)(4)(ii), which states that facilities must transfer mammographic films and records to other facilities or the patient at the patient's request, but stated that it was not economical or practical to copy films for the sake of keeping them in the patient's medical record.

FDA notes that § 900.12(c)(4)(ii) does not require that a facility maintain copies of a patient's medical records if the patient has asked to have them transferred elsewhere. The facility is free to determine for itself whether it is desirable to copy films for its own records.

Several comments stated that proposed § 900.4(c), which requires clinical image review as part of the accreditation and reaccreditation process, would be extremely costly and time-consuming. This burden includes the time and expense of choosing the images and having them copied and mailed. Another comment supported clinical image review as the best approach for a performance-based standard, but also stated that it would be costly and time-consuming.

FDA notes that Congress specifically required clinical image review as part of the accreditation and reaccreditation process (42 U.S.C. 263b((e)(1)(B)(i)), because clinical image review is necessary to ensure high quality mammography. While it may appear that the complexity of the process, and thus of the burden, has increased due to the increased detail in the final rule, these details are presently being followed as policy by the accreditation bodies so, in fact, there is no additional burden. The agency further notes that facilities are not required to copy the films before sending them for review. Only original films are reviewed and these are returned to the facility after the review is complete.

Several comments stated that § 900.12(e)(13), requiring facilities to establish an infection control procedure including documentation after each cleaning, would create needless paperwork and would not affect quality assurance.

FDA has included an additional paperwork burden estimate for this requirement in the final rule. Under § 900.12(e)(13), facilities are required to establish and comply with a system for cleaning and disinfecting equipment as needed. Although there is no evidence that blood-borne pathogens have been transmitted from patient to patient during mammography, there is a theoretical possibility of such a transmission. That agency believes the time required is justified to ease concerns about such a possibility, concerns that in some cases may cause patients to refuse to undergo mammography examinations and thus possibly lose the life-saving benefit of early detection of breast cancer.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve,

modify, or disapprove the information collection provisions in this final rule. 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.

## Appendix

### Excerpts from Chapter 4 of AHCPR's "Quality Determinants of Mammography;" Guidelines for Communicating Test Results

As noted previously, FDA recommends that mammography facilities utilize the AHCPR'S guidelines in ''Quality Determinants of Mammography'' with respect to written notification of results to patients. The pertinent information from Chapter 4 of those guidelines is reprinted here for ease of reference. The symbol [R] indicates that the AHCPR document provides an additional reference or references at that point.

**COMMUNICATING RESULTS**

RECOMMENDATION: The referring health care provider and the interpreting physician should be sensitive, supportive, and appropriate in communicating results, as well as prompt and accurate. (B)

STRONG RECOMMENDATION: An appropriate professional at the mammography facility, usually an interpreting physician, should send the woman's health care provider a written report documenting the specific findings, follow up recommendations, and the name of the interpreting physician. The facility should directly telephone the referring provider if the result is suspicious for cancer. (B)

STRONG RECOMMENDATION: The mammography facility personnel should give the woman written notification of the results of her mammography and other breast imaging, either on site or by mail. The results should be in simple language, document the name of the interpreting physician, be given in a timely fashion, and include further steps to be taken. (B)

RECOMMENDATION: If a facility accepts women who have no health care provider, facility personnel should give the woman a list of qualified providers who are willing to provide care. The name, address, and phone number of the provider chosen should be recorded, if possible (C).

STRONG RECOMMENDATION: The facility personnel should directly telephone the woman who has no health care provider if the result is suspicious for cancer (B).

Many women believe that mammography results are normal if they are not contacted after their examination. This impression that ''no news is good news'' can have serious adverse consequences for women with an abnormal examination. The interpreting physician, the referring health care provider, and the woman are all responsible for ensuring that mammography results are communicated in an effective and timely manner and that recommendations are carried out. Timely communication is necessary whether results are normal or abnormal (Table 3).

An increasing number of mammography facilities have begun to report both normal and abnormal results directly to the woman. This can be accomplished without disrupting the woman's relationship with her referring provider. Studies have shown that direct communication of results to the woman by the mammography facility produces a dramatic improvement in compliance with follow recommendations [R]. Traditional communication procedures, where the facility communicates only with the referring provider, result in inadequate compliance with follow up recommendations [R].

Problems in communicating abnormal results have included confusion concerning the appropriate steps to be taken; inappropriate or insensitive communication, resulting in avoidable anxiety and confusion; delay in receipt of results; and failure to communicate results to the woman at all—for example, when reports are misfiled or filed unread. These problems have caused delays in diagnosis and treatment, with consequences that include limited treatment options and death [R]. Providing results directly to the woman is a sound risk-management procedure, reducing the prospect of medicolegal complications for both the interpreting physician and the referring health care provider [R].

TABLE 3.—REPORTING OF RESULTS BY MAMMOGRAPHY FACILITY

| Outcome of Mammography Examination and Recommendation for Followup | Communication to Women—Oral (Onsite or by Telephone) | Communication to Women—Write (Onsite or Sent by Mail) | Phone Communication to Health Care Provider in Addition to Standard Report | Always Necessary Written Report to Health Care Provider |
|---|---|---|---|---|
| Normal | Optional | Strongly Recommended | None | Strongly Recommended |
| Abnormal: schedule additional imaging and/or ultrasonography | | | | |
| a) On line[1] | Recommended[2] | Strongly recommended[2] | Recommended[3] | Strongly recommended |
| b) Off line[1] | Optional[2] | Strongly recommended[2] | Recommended[3] | Strongly recommended |
| Abnormal: short-interval followup | Optional | Strongly recommended | Optional | Strongly recommended |
| Abnormal: Biopsy | Optional strongly recommended for self-referred women | Strongly recommended[4] | Strongly recommended | Strongly recommended |

[1] For an online study, the interpreting physician is present and reads the mammogram while the patient is there. For an offline study, the mammogram may be read after the woman leaves so the interpreting physician does not have to be present.

[2] For any patient for whom additional views or ultrasonography are recommended, a telephone call or discussion onsite with the patient may precede the written letter when the studies are to be performed immediately or within 2 days at that mammography facility. However, the results of the original and additional studies must be provided to the woman in writing.

[3] A telephone call from the mammography facility to the woman's designated physician or other health care provider is recommended. For self-referred patients, the telephone call should be made to the woman herself.

[4] For any patient without a direct referral, the mammography facility may wish to send the letter via registered or certified mail.

NOTE: Strong recommendations deal with elements of mammography that the panel considers essential to good practice. Recommendations deal with elements of mammography that the panel considers attainable in most but not all cases. Options are statements of a less compelling nature that cannot be justified as recommendations.

Communicating normal results directly to the woman as soon as possible eliminates anxiety, reinforces the woman's role as a responsible participant in the process, reminds the woman of the importance of regular screening, and is a quality assurance safeguard. Effective communication is most crucial when results are abnormal and additional imaging or other follow up is required. If findings are abnormal, the written results should detail steps the woman should take next.

Any written communication must have language that is carefully constructed to impart results without causing undue anxiety, to promote a relationship between the woman and a health care provider, and to encourage the woman to take the next step. [Note—the AHCPR publication provides several examples of letters for communicating results directly to women.]

Mammography facilities may accept self-requesting and self-referred women for mammography. Interpreting physicians have additional responsibilities for ensuring the effective communication of results for these women.

- Self-requesting woman. This woman comes for mammography on her own initiative but is able to name a personal physician or health care provider. Whether the woman is having screening or diagnostic mammography, the interpreting physician should document that the designated provider accepts responsibility for the woman's breast care before sending out the mammography report. In cases where the provider declines to accept the mammography report from the mammography facility, the facility should treat the woman as if she were self-referred.
- Self-referred woman. This is a woman who comes for mammography but has no personal health care provider or for whom the provider declines responsibility. Whether the woman is having screening or diagnostic mammography, the interpreting physician assumes responsibility for the woman's breast care, including education, physical examination, and communication of mammography results directly to the patient in understandable language. Mammography facility personnel should give the woman a list of qualified providers. If the woman chooses a provider from a list provided by the mammography facility, the interpreting physician should ensure that the chosen clinician will assume responsibility for the woman's breast care. Although self-referral has improved access to mammography, it has increased the responsibilities of the interpreting physician and created more possibilities for failure to communicate abnormal results.

STRONG RECOMMENDATION: At the time of the examination, mammography facility personnel should inform all women of the time period in which they will receive their results and of the possibility that prior films may need to be obtained. The woman should also be instructed to call the mammography facility or her health care provider if she does not receive her results within the stated time period. The facility should report results to the woman's provider and to the woman within the shortest practical time period. (B)

RECOMMENDATION: The facility should use its best efforts to send a report to the referring health care provider and to send results to the woman as soon as possible, usually within 10 business days. The reporting period should not exceed 30 days. (B)

STRONG RECOMMENDATION: The interpreting physician or designee should telephone the results of an abnormal examination that requires needle or open biopsy to the referring (or designated) health care provider's office in a timely manner. (B)

RECOMMENDATION: The interpreting physician or designee should telephone the results of an abnormal examination that requires additional views and/or ultrasonography in a timely manner to the referring (or designated) health care provider's office. (B)

OPTIONAL: The interpreting physician or the referring (or designated) health care provider may telephone the woman directly to explain abnormal findings, their significance, and recommended next steps. (B)

Mammography facility personnel should telephone the referring or designated health care provider because the written report may not reach the provider or may not arrive in time for the provider to respond to questions from the patient. A telephone call also enables the provider to ask questions about the report and to discuss follow up options with the interpreting physician [R].

When mammography results are abnormal, a telephone call to the woman's designated health care provider before a report is sent may identify and resolve any vagueness in the provider-patient status. For a self-requesting woman with an abnormal finding, this call will significantly reduce the chance that she will slip through the cracks.

If the woman does not have a provider or if the provider declines to accept the report, the interpreting physician or designee should call the woman directly to explain the result and the recommended next steps. This telephone communication is in addition to the written report and should offer the option to have the results explained in person. Information should not be left on an answering machine or given to another individual without the woman's express prior permission. Particularly for the woman without a referring provider, the mammography facility may choose to send written notification of abnormal results by certified mail or with return receipt requested. Mammography facility personnel should document the communication to the referring provider or the woman in the woman's medical record. Recommended reporting is outlined on Table 3.''

Chapter 6 of the AHCPR document also provides more information on the communication responsibilities of the interpreting physician.

## VII. References

The following references have been placed 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. Ries, L. A. G., B. A. Miller, and B. F. Hankey, et al. (Eds.), ''SEER Cancer Statistics Review, 1973–1991,'' National Cancer Institute, NIH Pub. No. 94–2789, Bethesda, MD, 1994.

2. AHCPR, ''Quality Determinants of Mammography,'' AHCPR Pub. No. 95–0632, October, 1994.

3. U.S. GAO, ''Mammography Services Initial Impact of New Federal Law Has Been Positive,'' GAO/HEHS–96–17, October, 1995.

4. Linver, M. N., J. R. Osuch, R. J. Brenner, and R. A. Smith, ''The Mammography Audit: A Primer for the Mammography Quality Standards Act (MQSA),'' *American Journal of Radiology*, 1995; 165:19–25.

5. CDC, ''Use of Mammography Services by Women Aged ≤ 65 Years Enrolled in Medicare—United States, 1995–1993,'' 1995; 44:777–781.

## List of Subjects

*21 CFR Part 16*

Administrative practice and procedure.

*21 CFR Part 900*

Electronic products, Health facilities, Mammography, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 16 and 900 are amended as follows:

## PART 16—REGULATORY HEARINGS BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 is revised to read as follows:

**Authority:** 21 U.S.C. 41–40, 141–149, 321–394, 467f, 679, 821, 1034; 42 U.S.C. 201–262, 263b, 364; 15 U.S.C. 1451–1461, 28 U.S.C. 2112.

2. Section 16.1 is amended in paragraph (b)(2) by numerically adding entries for §§ 900.7 and 900.14 to read as follows:

### § 716.1 Scope.

* * * * *

(b) * * *

(2) Regulatory provisions:

* * * * *

§ 900.7, relating to approval, reapproval, or withdrawal of approval of mammography accreditation bodies or rejection of a proposed fee for accreditation.

§ 900.14, relating to suspension or revocation of a mammography certificate.

* * * * *

3. 21 CFR Part 900 is revised to read as follows:

## PART 900—MAMMOGRAPHY

### Subpart A—Accreditation

Sec.
900.1 Scope.
900.2 Definitions.
900.3 Application for approval as an accreditation body.
900.4 Standards for accreditation bodies.
900.5 Evaluation.
900.6 Withdrawal of approval.
900.7 Hearings.
900.8–900.9 [Reserved]

### Subpart B—Quality Standards and Certification

900.10 Applicability.
900.11 Requirements for certification.
900.12 Quality standards.
900.13 Revocation of accreditation and revocation of accreditation body approval.
900.14 Suspension or revocation of certificates.

900.15 Appeals of adverse accreditation or reaccreditation decisions that preclude certification or recertification.
900.16 Appeals of denials of certification.
900.17 [Reserved]
900.18 Alternative requirements for § 900.12 quality standards.

**Authority:** 21 U.S.C. 360i, 360nn, 374(e); 42 U.S.C. 263b.

## Subpart A—Accreditation

### § 900.1 Scope.

The regulations set forth in this part implement the Mammography Quality Standards Act (MQSA) (42 U.S.C. 263b). Subpart A of this part establishes procedures whereby an entity can apply to become a Food and Drug Administration (FDA)-approved accreditation body to accredit facilities to be eligible to perform screening or diagnostic mammography services. Subpart A further establishes requirements and standards for accreditation bodies to ensure that all mammography facilities under the jurisdiction of the United States are adequately and consistently evaluated for compliance with national quality standards for mammography. Subpart B of this part establishes minimum national quality standards for mammography facilities to ensure safe, reliable, and accurate mammography. The regulations set forth in this part do not apply to facilities of the Department of Veterans Affairs.

### § 900.2 Definitions.

The following definitions apply to subparts A and B of this part:

(a) *Accreditation body* or *body* means an entity that has been approved by FDA under § 900.3(d) to accredit mammography facilities.

(b) *Action limits* or *action levels* means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

(c) *Adverse event* means an undesirable experience associated with mammography activities within the scope of 42 U.S.C. 263b. Adverse events include but are not limited to:

(1) Poor image quality;

(2) Failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and

(3) Use of personnel that do not meet the applicable requirements of § 900.12(a).

(d) *Air kerma* means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For X-rays with energies less than 300 kiloelectronvolts (keV), 1 Gy = 100 radian (rad) = 114 roentgens (R) of exposure.

(e) *Breast implant* means a prosthetic device implanted in the breast.

(f) *Calendar quarter* means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.

(g) *Category I* means medical educational activities that have been designated as Category I by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society, or an equivalent organization.

(h) *Certificate* means the certificate described in § 900.11(a).

(i) *Certification* means the process of approval of a facility by FDA to provide mammography services.

(j) *Clinical image* means a mammogram.

(k) *Consumer* means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

(l) *Continuing education unit* or *continuing education credit* means one contact hour of training.

(m) *Contact hour* means an hour of training received through direct instruction.

(n) *Direct instruction* means:

(1) Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or

(2) The administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

(o) *Direct supervision* means that:

(1) During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records; or

(2) During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

(p) *Established operating level* means the value of a particular quality assurance parameter that has been established as an acceptable normal level by the facility's quality assurance program.

(q) *Facility* means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: Operation of equipment to produce a mammogram, processing of the mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. This term does not include a facility of the Department of Veterans Affairs.

(r) *First allowable time* means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body. The ''first allowable time'' may vary with the certifying body.

(s) *FDA* means the Food and Drug Administration.

(t) *Interim regulations* means the regulations entitled ''Requirements for Accrediting Bodies of Mammography Facilities'' (58 FR 67558–67565) and ''Quality Standards and Certification Requirements for Mammography Facilities'' (58 FR 67565–67572), published by FDA on December 21, 1993, and amended on September 30, 1994 (59 FR 49808–49813). These regulations established the standards that had to be met by mammography facilities in order to lawfully operate between October 1, 1994, and April 28, 1999.

(u) *Interpreting physician* means a licensed physician who interprets mammograms and who meets the requirements set forth in § 900.12(a)(1).

(v) *Kerma* means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

(w) *Laterality* means the designation of either the right or left breast.

(x) *Lead interpreting physician* means the interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of § 900.12(d) through (f). The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

(y) *Mammogram* means a radiographic image produced through mammography.

(z) *Mammographic Modality* means a technology, within the scope of 42 U.S.C. 263b, for radiography of the breast. Examples are screen-film mammography and xeromammography.

(aa) *Mammography* means radiography of the breast, but, for the purposes of this part, does not include:

(1) Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or

(2) Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter.

(bb) *Mammography equipment evaluation* means an onsite assessment of mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards in § 900.12(b) and (e).

(cc) *Mammography medical outcomes audit* means a systematic collection of mammography results and the comparison of those results with outcomes data.

(dd) *Mammography unit* or *units* means an assemblage of components for the production of X-rays for use during mammography, including, at a minimum: An X-ray generator, an X-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

(ee) *Mean optical density* means the average of the optical densities measured using phantom thicknesses of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

(ff) *Medical physicist* means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in § 900.12(a)(3).

(gg) *MQSA* means the Mammography Quality Standards Act.

(hh) *Multi-reading* means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram.

(ii) *Patient* means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

(jj) *Phantom* means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

(kk) *Phantom image* means a radiographic image of a phantom.

(ll) *Physical science* means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

(mm) *Positive mammogram* means a mammogram that has an overall assessment of findings that are either ''suspicious'' or ''highly suggestive of malignancy.''

(nn) *Provisional certificate* means the provisional certificate described in § 900.11(b)(2).

(oo) *Qualified instructor* means an individual whose training and experience adequately prepares him or her to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of § 900.12(a) would be considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this part include, but are not limited to, instructors in a post-high school training institution and manufacturer's representatives.

(pp) *Quality control technologist* means an individual meeting the requirements of § 900.12(a)(2) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

(qq) *Radiographic equipment* means X-ray equipment used for the production of static X-ray images.

(rr) *Radiologic technologist* means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and who meets the requirements set forth in § 900.12(a)(2).

(ss) *Serious adverse event* means an adverse advent that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

(tt) *Serious complaint* means a report of a serious adverse event.

(uu) *Standard breast* means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.

(vv) *Survey* means an onsite physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.

(ww) *Time cycle* means the film development time.

(xx) *Traceable to a national standard* means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every 2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within ± 3 percent of the national standard in the mammography energy range.

**§ 900.3 Application for approval as an accreditation body.**

(a) *Eligibility.* Private nonprofit organizations or State agencies capable of meeting the requirements of this subpart A may apply for approval as accreditation bodies.

(b) *Application for initial approval.* (1) An applicant seeking initial FDA approval as an accreditation body shall inform the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiology Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, marked Attn: Mammography Standards Branch, of its desire to be approved as an accreditation body and of its requested scope of authority.

(2) Following receipt of the request, FDA will provide the applicant with additional information to aid in submission of an application for approval as an accreditation body.

(3) The applicant shall furnish to FDA, at the address in § 900.3(b)(1), three copies of an application containing the following information, materials, and supporting documentation:

(i) Name, address, and phone number of the applicant and, if the applicant is not a State agency, evidence of nonprofit status (i.e., of fulfilling Internal Revenue Service requirements as a nonprofit organization);

(ii) Detailed description of the accreditation standards the applicant will require facilities to meet and a discussion substantiating their equivalence to FDA standards required under § 900.12;

(iii) Detailed description of the applicant's accreditation review and decisionmaking process, including:

(A) Procedures for performing accreditation and reaccreditation clinical image review in accordance with § 900.4(c), random clinical image reviews in accordance with § 900.4(f), and additional mammography review in accordance with § 900.12(j);

(B) Procedures for performing phantom image review;

(C) Procedures for assessing mammography equipment evaluations and surveys;

(D) Procedures for initiating and performing onsite visits to facilities;

(E) Procedures for assessing facility personnel qualifications;

(F) Copies of the accreditation application forms, guidelines, instructions, and other materials the applicant will send to facilities during the accreditation process, including an accreditation history form that requires each facility to provide a complete history of prior accreditation activities and a statement that all information and data submitted in the application is true and accurate, and that no material fact has been omitted;

(G) Policies and procedures for notifying facilities of deficiencies;

(H) Procedures for monitoring corrections of deficiencies by facilities;

(I) Policies and procedures for suspending or revoking a facility's accreditation;

(J) Policies and procedures that will ensure processing of accreditation applications and renewals within a timeframe approved by FDA and assurances that the body will adhere to such policies and procedures; and

(K) A description of the applicant's appeals process for facilities contesting adverse accreditation status decisions.

(iv) Education, experience, and training requirements for the applicant's professional staff, including reviewers of clinical or phantom images;

(v) Description of the applicant's electronic data management and analysis system with respect to accreditation review and decision processes and the applicant's ability to provide electronic data in a format compatible with FDA data systems;

(vi) Resource analysis that demonstrates that the applicant's staffing, funding, and other resources are adequate to perform the required accreditation activities;

(vii) Fee schedules with supporting cost data;

(viii) Statement of policies and procedures established to avoid conflicts of interest or the appearance of conflicts of interest by the applicant's board members, commissioners, professional personnel (including reviewers of clinical and phantom images), consultants, administrative personnel, and other representatives of the applicant;

(ix) Statement of policies and procedures established to protect confidential information the applicant will collect or receive in its role as an accreditation body;

(x) Disclosure of any specific brand of imaging system or component, measuring device, software package, or other commercial product used in mammography that the applicant develops, sells, or distributes;

(xi) Description of the applicant's consumer complaint mechanism;

(xii) Satisfactory assurances that the applicant shall comply with the requirements of § 900.4; and

(xiii) Any other information as may be required by FDA.

(c) *Application for renewal of approval.* An approved accreditation body that intends to continue to serve as an accreditation body beyond its current term shall apply to FDA for renewal or notify FDA of its plans not to apply for renewal in accordance with the following procedures and schedule:

(1) At least 9 months before the date of expiration of a body's approval, the body shall inform FDA, at the address given in § 900.3(b)(1), of its intent to seek renewal.

(2) FDA will notify the applicant of the relevant information, materials, and supporting documentation required under § 900.3(b)(3) that the applicant shall submit as part of the renewal procedure.

(3) At least 6 months before the date of expiration of a body's approval, the applicant shall furnish to FDA, at the address in § 900.3(b)(1), three copies of a renewal application containing the information, materials, and supporting documentation requested by FDA in accordance with § 900.3(c)(2).

(4) No later than July 28, 1998 any accreditation body approved under the interim regulations published in the **Federal Register** of December 21, 1993 (58 FR 67558), that desires to continue to serve as an accreditation body under the final regulations shall apply for renewal of approval in accordance with the procedures set forth in paragraphs (c)(1) through (c)(3) of this section.

(5) Any accreditation body that does not plan to renew its approval shall so notify FDA at the address given in paragraph (b)(1) of this section at least 9 months before the expiration of the body's term of approval.

(d) *Rulings on applications for initial and renewed approval.* (1) FDA will conduct a review and evaluation to determine whether the applicant substantially meets the applicable requirements of this subpart and whether the accreditation standards the applicant will require facilities to meet are substantially the same as the quality standards published under subpart B of this part.

(2) FDA will notify the applicant of any deficiencies in the application and request that those deficiencies be rectified within a specified time period. If the deficiencies are not rectified to FDA's satisfaction within the specified time period, the application for approval as an accreditation body may be rejected.

(3) FDA shall notify the applicant whether the application has been approved or denied. That notification shall list any conditions associated with approval or state the bases for any denial.

(4) The review of any application may include a meeting between FDA and representatives of the applicant at a time and location mutually acceptable to FDA and the applicant.

(5) FDA will advise the applicant of the circumstances under which a denied application may be resubmitted.

(6) If FDA does not reach a final decision on a renewal application in accordance with this paragraph before the expiration of an accreditation body's current term of approval, the approval will be deemed extended until the agency reaches a final decision on the application, unless an accreditation body does not rectify deficiencies in the application within the specified time period, as required in paragraph (d)(2) of this section.

(e) *Relinquishment of authority.* An accreditation body that decides to relinquish its accreditation authority before expiration of the body's term of approval shall submit a letter of such intent to FDA, at the address in § 900.3(b)(1), at least 9 months before relinquishing such authority.

(f) *Transfer of records.* An accreditation body that does not apply for renewal of accreditation body approval, is denied such approval by FDA, or relinquishes its accreditation authority and duties before expiration of its term of approval, shall:

(1) Transfer facility records and other related information as required by FDA to a location and according to a schedule approved by FDA.

(2) Notify, in a manner and time period approved by FDA, all facilities accredited or seeking accreditation by the body that the body will no longer have accreditation authority.

(g) *Scope of authority.* An accreditation body's term of approval is for a period not to exceed 7 years. FDA may limit the scope of accreditation authority.

**§ 900.4 Standards for accreditation bodies.**

(a) *Code of conduct and general responsibilities.* The accreditation body shall accept the following responsibilities in order to ensure safe and accurate mammography at the facilities it accredits and shall perform these responsibilities in a manner that ensures the integrity and impartiality of accreditation body actions.

(1)(i) When an accreditation body receives or discovers information that suggests inadequate image quality, or upon request by FDA, the accreditation body shall review a facility's clinical images or other aspects of a facility's practice to assist FDA in determining whether or not the facility's practice poses a serious risk to human health. Such reviews are in addition to the evaluation an accreditation body performs as part of the initial accreditation or renewal process for facilities.

(ii) If review by the accreditation body demonstrates that a problem does exist with respect to image quality or other aspects of a facility's compliance with quality standards, or upon request by FDA, the accreditation body shall require or monitor corrective actions, or suspend or revoke accreditation of the facility.

(2) The accreditation body shall inform FDA as soon as possible but in no case longer than 2 business days after becoming aware of equipment or practices that pose a serious risk to human health.

(3) The accreditation body shall establish and administer a quality assurance (QA) program that has been approved by FDA in accordance with § 900.3(d) or paragraph (a)(8) of this section. Such quality assurance program shall:

(i) Include requirements for clinical image review and phantom image review;

(ii) Ensure that clinical and phantom images are evaluated consistently and accurately; and

(iii) Specify the methods and frequency of training and evaluation for clinical and phantom image reviewers, and the bases and procedures for removal of such reviewers.

(4) The accreditation body shall establish measures that FDA has approved in accordance with § 900.3(d) or paragraph (a)(8) of this section to reduce the possibility of conflict of interest or facility bias on the part of individuals acting on the body's behalf. Such individuals who review clinical or phantom images under the provisions of paragraphs (c) and (d) of this section or who visit facilities under the provisions of paragraph (f) of this section shall not review clinical or phantom images from or visit a facility with which such individuals maintain a financial relationship, or when it would otherwise be a conflict of interest for them to do so, or when they have a bias in favor of or against the facility.

(5) The accreditation body may require specific equipment performance or design characteristics that FDA has approved. However, no accreditation body shall require, either explicitly or implicitly, the use of any specific brand of imaging system or component, measuring device, software package, or other commercial product as a condition for accreditation by the body, unless FDA determines that it is in the best interest of public health to do so.

(i) Any representation, actual or implied, either orally, in sales literature, or in any other form of representation, that the purchase or use of a particular product brand is required in order for any facility to be accredited or certified under § 900.11(b), is prohibited, unless FDA approves such representation.

(ii) Unless FDA has approved the exclusive use and promotion of a particular commercial product in accordance with this section, all products produced, distributed, or sold by an accreditation body or an organization that has a financial or other relationship with the accreditation body that may be a conflict of interest or have the appearance of a conflict of interest with the body's accreditation functions, shall bear a disclaimer stating that the purchase or use of such products is not required for accreditation or certification of any facility under § 900.11(b). Any representations about such products shall include a similar disclaimer.

(6) When an accreditation body denies accreditation to a facility, the accreditation body shall notify the facility in writing and explain the bases for its decision. The notification shall also describe the appeals process available from the accreditation body for the facility to contest the decision.

(7) No accreditation body may establish requirements that preclude facilities from being accredited under § 900.11(b) by any other accreditation body, or require accreditation by itself under MQSA if another accreditation body is available to a facility.

(8) The accreditation body shall obtain FDA authorization for any changes it proposes to make in any standards that FDA has previously accepted under § 900.3(d).

(9) An accreditation body shall establish procedures to protect confidential information it collects or receives in its role as an accreditation body.

(i) Nonpublic information collected from facilities for the purpose of carrying out accreditation body responsibilities shall not be used for any other purpose or disclosed, other than to FDA or its duly designated representatives, including State agencies, without the consent of the facility;

(ii) Nonpublic information that FDA or its duly designated representatives, including State agencies, share with the accreditation body concerning a facility that is accredited or undergoing accreditation by that body shall not be further disclosed except with the written permission of FDA.

(b) *Monitoring facility compliance with quality standards.* (1) The accreditation body shall require that each facility it accredits meet standards for the performance of quality mammography that are substantially the same as those in this subpart and in subpart B of this part.

(2) The accreditation body shall notify a facility regarding equipment, personnel, and other aspects of the facility's practice that do not meet such standards and advise the facility that such equipment, personnel, or other aspects of the practice should not be used by the facility for activities within the scope of part 900.

(3) The accreditation body shall specify the actions that facilities shall take to correct deficiencies in equipment, personnel, and other aspects of the practice to ensure facility compliance with applicable standards.

(4) If deficiencies cannot be corrected to ensure compliance with standards or if a facility is unwilling to take corrective actions, the accreditation body shall immediately so notify FDA, and shall suspend or revoke the facility's accreditation in accordance with the policies and procedures described under § 900.3(b)(3)(iii)(I).

(c) *Clinical image review for accreditation and reaccreditation.* (1) Frequency of review. The accreditation body shall review clinical images from each facility accredited by the body at least once every 3 years.

(2) Requirements for clinical image attributes. The accreditation body shall use the following attributes for all clinical image reviews, unless FDA has approved other attributes:

(i) Positioning. Sufficient breast tissue shall be imaged to ensure that cancers are not likely to be missed because of inadequate positioning.

(ii) Compression. Compression shall be applied in a manner that minimizes the potential obscuring effect of overlying breast tissue and motion artifact.

(iii) Exposure level. Exposure level shall be adequate to visualize breast structures. Images shall be neither underexposed nor overexposed.

(iv) Contrast. Image contrast shall permit differentiation of subtle tissue density differences.

(v) Sharpness. Margins of normal breast structures shall be distinct and not blurred.

(vi) Noise. Noise in the image shall not obscure breast structures or suggest the appearance of structures not actually present.

(vii) Artifacts. Artifacts due to lint, processing, scratches, and other factors external to the breast shall not obscure breast structures or suggest the appearance of structures not actually present.

(viii) Examination identification. Each image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(A) Name of the patient and an additional patient identifier.

(B) Date of examination.

(C) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by FDA in accordance with § 900.3(d) or paragraph (a)(8) of this section shall be used to identify view and laterality.

(D) Facility name and location. At a minimum, the location shall include the city, State, and zip code of the facility.

(E) Technologist identification.

(F) Cassette/screen identification.

(G) Mammography unit identification, if there is more than one unit in the facility.

(3) Scoring of clinical images. Accreditation bodies shall establish and administer a system for scoring clinical images using all attributes specified in paragraphs (c)(2)(i) through (c)(2)(viii) of this section or an alternative system that FDA has approved in accordance with § 900.3(d) or paragraph (a)(8) of this section. The scoring system shall include an evaluation for each attribute.

(i) The accreditation body shall establish and employ criteria for acceptable and nonacceptable results for each of the 8 attributes as well as an overall pass-fail system for clinical image review that has been approved by FDA in accordance with § 900.3(d) or paragraph (a)(8) of this section.

(ii) All clinical images submitted by a facility to the accreditation body shall be reviewed independently by two or more clinical image reviewers.

(4) Selection of clinical images for review. Unless otherwise specified by FDA, the accreditation body shall require that for each mammography unit in the facility:

(i) The facility shall submit craniocaudal (CC) and mediolateral oblique (MLO) views from two mammographic examinations that the facility produced during a time period specified by the accreditation body;

(ii) Clinical images submitted from one such mammographic examination for each unit shall be of dense breasts (predominance of glandular tissue) and the other shall be of fat-replaced breasts (predominance of adipose tissue);

(iii) All clinical images submitted shall be images that the facility's interpreting physician(s) interpreted as negative or benign.

(iv) If the facility has no clinical images meeting the requirements in paragraphs (c)(4)(i) through (c)(4)(iii) of this section, it shall so notify the accreditation body, which shall specify alternative clinical image selection methods that do not compromise care of the patient.

(5) Clinical image reviewers. Accreditation bodies shall ensure that all of their clinical image reviewers:

(i) Meet the interpreting physician requirements specified in § 900.12(a)(1);

(ii) Are trained and evaluated in the clinical image review process, for the types of clinical images to be evaluated by a clinical image reviewer, by the accreditation body before designation as clinical image reviewers and periodically thereafter; and

(iii) Clearly document their findings and reasons for assigning a particular score to any clinical image and provide information to the facility for use in improving the attributes for which significant deficiencies were identified.

(6) Image management. The accreditation body's QA program shall include a tracking system to ensure the security and return to the facility of all clinical images received and to ensure completion of all clinical image reviews by the body in a timely manner. The accreditation body shall return all clinical images to the facility within 60 days of their receipt by the body, with the following exceptions:

(i) If the clinical images are needed earlier by the facility for clinical purposes, the accreditation body shall cooperate with the facility to accommodate such needs.

(ii) If a clinical image reviewer identifies a suspicious abnormality on an image submitted for clinical image review, the accreditation body shall ensure that this information is provided to the facility and that the clinical images are returned to the facility. Both shall occur no later than 10 business days after identification of the suspected abnormality.

(7) Notification of unsatisfactory image quality. If the accreditation body determines that the clinical images received from a facility are of unsatisfactory quality, the body shall notify the facility of the nature of the problem and its possible causes.

(d) *Phantom image review for accreditation and reaccreditation.* (1) Frequency of review. The accreditation body shall review phantom images from each facility accredited by the body at least once every 3 years.

(2) Requirements for the phantom used. The accreditation body shall require that each facility submit for review phantom images that the facility produced using a phantom and methods of use specified by the body and approved by FDA in accordance with § 900.3(d) or paragraph (a)(8) of this section.

(3) Scoring phantom images. The accreditation body shall use a system for scoring phantom images that has been approved by FDA in accordance with § 900.3(b) and (d) or paragraph (a)(8) of this section.

(4) Phantom images selected for review. For each mammography unit in the facility, the accreditation body shall require the facility to submit phantom images that the facility produced during a time period specified by the body.

(5) Phantom image reviewers. Accreditation bodies shall ensure that all of their phantom image reviewers:

(i) Meet the requirements specified in § 900.12(a)(3) or alternative requirements established by the accreditation body and approved by FDA in accordance with § 900.3 or paragraph (a)(8) of this section;

(ii) Are trained and evaluated in the phantom image review process, for the types of phantom images to be evaluated by a phantom image reviewer, by the accreditation body before designation as phantom image reviewers and periodically thereafter; and

(iii) Clearly document their findings and reasons for assigning a particular score to any phantom image and provide information to the facility for use in improving its phantom image quality with regard to the significant deficiencies identified.

(6) Image management. The accreditation body's QA program shall include a tracking system to ensure the security of all phantom images received and to ensure completion of all phantom image reviews by the body in a timely manner. All phantom images that result in a failure of accreditation shall be returned to the facility.

(7) Notification measures for unsatisfactory image quality. If the accreditation body determines that the phantom images received from a facility are of unsatisfactory quality, the body shall notify the facility of the nature of the problem and its possible causes.

(e) *Reports of mammography equipment evaluation, surveys, and quality control.* The following requirements apply to all facility equipment covered by the provisions of subparts A and B:

(1) The accreditation body shall require every facility applying for accreditation to submit:

(i) With its initial accreditation application, a mammography equipment evaluation that was performed by a medical physicist no earlier than 6 months before the date of application for accreditation by the facility. Such evaluation shall demonstrate compliance of the facility's equipment with the requirements in § 900.12(e).

(ii) Prior to accreditation, a survey that was performed no earlier than 6 months before the date of application for accreditation by the facility. Such survey shall assess the facility's compliance with the facility standards referenced in paragraph (b) of this section.

(2) The accreditation body shall require that all facilities undergo an annual survey to ensure continued compliance with the standards referenced in paragraph (b) of this section and to provide continued oversight of facilities' quality control programs as they relate to such standards. The accreditation body shall require for all facilities that:

(i) Such surveys be conducted annually;

(ii) Facilities take reasonable steps to ensure that they receive reports of such surveys within 30 days of survey completion; and

(iii) Facilities submit the results of such surveys and any other information that the body may require to the body at least annually.

(3) The accreditation body shall review and analyze the information required in this section and use it to identify necessary corrective measures for facilities and to determine whether facilities should remain accredited by the body.

(f) *Accreditation Body Onsite Visits and Random Clinical Image Reviews.* The accreditation body shall conduct onsite visits and random clinical image reviews of a sample of facilities to monitor and assess their compliance with standards established by the body for accreditation. The accreditation body shall submit annually to FDA, at the address given in § 900.3(b)(1), 3 copies of a summary report describing all facility assessments the body conducted under the provisions of this section for the year being reported.

(1) Onsite visits. (i) Sample size. Annually, each accreditation body shall visit at least 5 percent of the facilities it accredits. However, a minimum of 5 facilities shall be visited, and visits to no more than 50 facilities are required, unless problems identified in paragraph (f)(1)(i)(B) of this section indicate a need to visit more than 50 facilities.

(A) At least 50 percent of the facilities visited shall be selected randomly.

(B) Other facilities visited shall be selected based on problems identified through State or FDA inspections, serious complaints received from consumers or others, a previous history of noncompliance, or any other information in the possession of the accreditation body, inspectors, or FDA.

(C) Before, during, or after any facility visit, the accreditation body may require that the facility submit to the body for review clinical images, phantom images, or any other information relevant to applicable standards in this subpart and in subpart B of this part.

(ii) Visit plan. The accreditation body shall conduct facility onsite visits according to a visit plan that has been approved by FDA in accordance with § 900.3(d) or paragraph (a)(8) of this section, unless otherwise directed by FDA in particular circumstances. At a minimum, such a plan shall provide for:

(A) Assessment of overall clinical image QA activities of the facility;

(B) Review of facility documentation to determine if appropriate mammography reports are sent to patients and physicians as required;

(C) Selection of a sample of clinical images for clinical image review by the accreditation body. Clinical images shall be selected in a manner specified by the accreditation body and approved by FDA that does not compromise care of the patient as a result of the absence of the selected images from the facility;

(D) Verification that the facility has a medical audit system in place and is correlating films and pathology reports for positive cases;

(E) Verification that personnel specified by the facility are the ones actually performing designated personnel functions;

(F) Verification that equipment specified by the facility is the equipment that is actually being used to perform designated equipment functions;

(G) Verification that a consumer complaint mechanism is in place and that the facility is following its procedures; and

(H) Review of all factors related to previously identified concerns or concerns identified during that visit.

(2) Clinical image review for random sample of facilities. (i) Sample size. In addition to conducting clinical image reviews for accreditation and reaccreditation for all facilities, the accreditation body shall conduct clinical image reviews annually for a randomly selected sample as specified by FDA, but to include at least 3 percent of the facilities the body accredits. Accreditation bodies may count toward this random sample requirement all facilities selected randomly for the onsite visits described in paragraph (f)(1)(i)(A) of this section. Accreditation bodies shall not count toward the random sample requirement any facilities described in paragraph (f)(1)(i)(B) of this section that were selected for a visit because of previously identified concerns.

(ii) Random clinical image review. In performing clinical image reviews of the random sample of facilities, accreditation bodies shall evaluate the same attributes as those in paragraph (c) of this section for review of clinical images for accreditation and reaccreditation.

(iii) Accreditation bodies should not schedule random clinical image reviews at facilities that have received notification of the need to begin the accreditation renewal process or that have completed the accreditation renewal process within the previous 6 months.

(iv) Selection of the random sample of clinical images for clinical image review by the accreditation body. Clinical images shall be selected in a manner, specified by the accreditation body and approved by FDA under § 900.3(d) or paragraph (a)(8) of this section, that does not compromise care of the patient as a result of the absence of the selected images from the facility.

(g) *Consumer complaint mechanism.* The accreditation body shall develop and administer a written and documented system, including timeframes, for collecting and resolving serious consumer complaints that could not be resolved at a facility. Such system shall have been approved by FDA in accordance with§ 900.3(d) or paragraph (a)(8) of this section. Accordingly, all accreditation bodies shall:

(1) Provide a mechanism for all facilities it accredits to file serious unresolved complaints with the accreditation body;

(2) Maintain a record of every serious unresolved complaint received by the body on all facilities it accredits for a period of at least 3 years from the date of receipt of each such complaint;

(h) *Reporting and recordkeeping.* All reports to FDA specified in paragraphs (h)(1) through (h)(4) of this section shall be prepared and submitted in a format

and medium prescribed by FDA and shall be submitted to a location and according to a schedule specified by FDA. The accreditation body shall:

(1) Collect and submit to FDA the information required by 42 U.S.C. 263b(d) for each facility when the facility is initially accredited and at least annually when updated, in a manner and at a time specified by FDA.

(2) Accept applications containing the information required in 42 U.S.C. 263b(c)(2) for provisional certificates and in § 900.11(b)(3) for extension of provisional certificates, on behalf of FDA, and notify FDA of the receipt of such information;

(3) Submit to FDA the name, identifying information, and other information relevant to 42 U.S.C. 263b and specified by FDA for any facility for which the accreditation body denies, suspends, or revokes accreditation, and the reason(s) for such action;

(4) Submit to FDA an annual report summarizing all serious complaints received during the previous calendar year, their resolution status, and any actions taken in response to them;

(5) Provide to FDA other information relevant to 42 U.S.C. 263b and required by FDA about any facility accredited or undergoing accreditation by the body.

(i) *Fees.* Fees charged to facilities for accreditation shall be reasonable. Costs of accreditation body activities that are not related to accreditation functions under 42 U.S.C. 263b are not recoverable through fees established for accreditation.

(1) The accreditation body shall make public its fee structure, including those factors, if any, contributing to variations in fees for different facilities.

(2) At FDA's request, accreditation bodies shall provide financial records or other material to assist FDA in assessing the reasonableness of accreditation body fees. Such material shall be provided to FDA in a manner and time period specified by the agency.

**§ 900.5 Evaluation.**

FDA shall evaluate annually the performance of each accreditation body. Such evaluation shall include an assessment of the reports of FDA or State inspections of facilities accredited by the body as well as any additional information deemed relevant by FDA that has been provided by the accreditation body or other sources or has been required by FDA as part of its oversight initiatives. The evaluation shall include a determination of whether there are major deficiencies in the accreditation body's performance that, if not corrected, would warrant withdrawal of the approval of the accreditation body under the provisions of § 900.6.

**§ 900.6 Withdrawal of approval.**

If FDA determines, through the evaluation activities of § 900.5, or through other means, that an accreditation body is not in substantial compliance with this subpart, FDA may initiate the following actions:

(a) *Major deficiencies.* If FDA determines that an accreditation body has failed to perform a major accreditation function satisfactorily, has demonstrated willful disregard for public health, has violated the code of conduct, has committed fraud, or has submitted material false statements to the agency, FDA may withdraw its approval of that accreditation body.

(1) FDA shall notify the accreditation body of the agency's action and the grounds on which the approval was withdrawn.

(2) An accreditation body that has lost its approval shall notify facilities accredited or seeking accreditation by it that its approval has been withdrawn. Such notification shall be made within a time period and in a manner approved by FDA.

(b) *Minor deficiencies.* If FDA determines that an accreditation body has demonstrated deficiencies in performing accreditation functions and responsibilities that are less serious or more limited than the deficiencies in paragraph (a) of this section, FDA shall notify the body that it has a specified period of time to take particular corrective measures directed by FDA or to submit to FDA for approval the body's own plan of corrective action addressing the minor deficiencies. FDA may place the body on probationary status for a period of time determined by FDA, or may withdraw approval of the body as an accreditation body if corrective action is not taken.

(1) If FDA places an accreditation body on probationary status, the body shall notify all facilities accredited or seeking accreditation by it of its probationary status within a time period and in a manner approved by FDA.

(2) Probationary status shall remain in effect until such time as the body can demonstrate to the satisfaction of FDA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and that the corrective actions have substantially eliminated all identified problems.

(3) If FDA determines that an accreditation body that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, FDA may withdraw approval of the accreditation body. The accreditation body shall notify all facilities accredited or seeking accreditation by it of its loss of FDA approval, within a time period and in a manner approved by FDA.

(c) *Reapplication by accreditation bodies that have had their approval withdrawn.* (1) A former accreditation body that has had its approval withdrawn may submit a new application for approval if the body can provide information to FDA to establish that the problems that were grounds for withdrawal of approval have been resolved.

(2) If FDA determines that the new application demonstrates that the body satisfactorily has addressed the causes of its previous unacceptable performance, FDA may reinstate approval of the accreditation body.

(3) FDA may request additional information or establish additional conditions that must be met by a former accreditation body before FDA approves the reapplication.

(4) FDA may refuse to accept an application from a former accreditation body whose approval was withdrawn because of fraud or willful disregard of public health.

**§ 900.7 Hearings.**

(a) Opportunities to challenge final adverse actions taken by FDA regarding approval or reapproval of accreditation bodies, withdrawal of approval of accreditation bodies, or rejection of a proposed fee for accreditation shall be communicated through notices of opportunity for informal hearings in accordance with part 16 of this chapter.

(b) A facility that has been denied accreditation is entitled to an appeals process from the accreditation body. The appeals process shall be specified in writing by the accreditation body and shall have been approved by FDA in accordance with § 900.3(d) or § 900.4(a)(8).

(c) A facility that cannot achieve satisfactory resolution of an adverse accreditation decision through the accreditation body's appeals process may appeal to FDA for reconsideration in accordance with § 900.15.

**§§ 900.8–900.9 [Reserved]**

**Subpart B—Quality Standards and Certification**

**§ 900.10 Applicability.**

The provisions of subpart B are applicable to all facilities under the regulatory jurisdiction of the United States that provide mammography

services, with the exception of the Department of Veterans Affairs.

**§ 900.11 Requirements for certification.**

(a) *General.* After October 1, 1994, a certificate issued by FDA is required for lawful operation of all mammography facilities subject to the provisions of this subpart. To obtain a certificate from FDA, facilities are required to meet the quality standards in § 900.12 and to be accredited by an approved accreditation body or other entity as designated by FDA.

(b) *Application.* (1) *Certificates.* (i) In order to qualify for a certificate, a facility must apply to an FDA-approved accreditation body, or to another entity designated by FDA. The facility shall submit to such body or entity the information required in 42 U.S.C. 263b(d)(1).

(ii) Following the agency's receipt of the accreditation body's decision to accredit a facility, or an equivalent decision by another entity designated by FDA, the agency may issue a certificate to the facility, or renew an existing certificate, if the agency determines that the facility has satisfied the requirements for certification or recertification.

(2) *Provisional certificates.* (i) A new facility beginning operation after October 1, 1994, is eligible to apply for a provisional certificate. The provisional certificate will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process. To apply for and receive a provisional certificate, a facility must meet the requirements of 42 U.S.C. 263b(c)(2) and submit the necessary information to an approved accreditation body or other entity designated by FDA.

(ii) Following the agency's receipt of the accreditation body's decision that a facility has submitted the required information, FDA may issue a provisional certificate to a facility upon determination that the facility has satisfied the requirements of § 900.11(b)(2)(i). A provisional certificate shall be effective for up to 6 months from the date of issuance. A provisional certificate cannot be renewed, but a facility may apply for a 90-day extension of the provisional certificate.

(3) *Extension of provisional certificate.* (i) To apply for a 90-day extension to a provisional certificate, a facility shall submit to its accreditation body, or other entity designated by FDA, a statement of what the facility is doing to obtain certification and evidence that there would be a significant adverse impact on access to mammography in the geographic area served if such facility did not obtain an extension.

(ii) The accreditation body shall forward the request, with its recommendation, to FDA within 2 business days after receipt.

(iii) FDA may issue a 90-day extension for a provisional certificate upon determination that the extension meets the criteria set forth in 42 U.S.C. 263b(c)(2).

(iv) There can be no renewal of a provisional certificate beyond the 90-day extension.

(c) *Reinstatement policy.* A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA, or that has had its certificate suspended or revoked by FDA, may apply to have the certificate reinstated so that the facility may be considered to be a new facility and thereby be eligible for a provisional certificate.

(1) Unless prohibited from reinstatement under § 900.11(c)(4), a facility applying for reinstatement shall:

(i) Contact an FDA-approved accreditation body or other entity designated by FDA to determine the requirements for reapplication for accreditation;

(ii) Fully document its history as a previously provisionally certified or certified mammography facility, including the following information:

(A) Name and address of the facility under which it was previously provisionally certified or certified;

(B) Name of previous owner/lessor;

(C) FDA facility identification number assigned to the facility under its previous certification; and

(D) Expiration date of the most recent FDA provisional certificate or certificate; and

(iii) Justify application for reinstatement of accreditation by submitting to the accreditation body or other entity designated by FDA, a corrective action plan that details how the facility has corrected deficiencies that contributed to the lapse of, denial of renewal, or revocation of its certificate.

(2) FDA may issue a provisional certificate to the facility if:

(i) The accreditation body or other entity designated by FDA notifies the agency that the facility has adequately corrected, or is in the process of correcting, pertinent deficiencies; and

(ii) FDA determines that the facility has taken sufficient corrective action since the lapse of, denial of renewal, or revocation of its previous certificate.

(3) After receiving the provisional certificate, the facility may lawfully resume performing mammography services while completing the requirements for certification.

(4) If a facility's certificate was revoked on the basis of an act described in 41 U.S.C. 263b(i)(1), no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility within 2 years of the date of revocation.

**§ 900.12 Quality standards.**

(a) *Personnel.* The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

(1) Interpreting physicians. All physicians interpreting mammograms shall meet the following qualifications:

(i) Initial qualifications. Unless the exemption in paragraph (a)(1)(iii)(A) of this section applies, before beginning to interpret mammograms independently, the interpreting physician shall:

(A) Be licensed to practice medicine in a State;

(B)(*1*) Be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography; or

(*2*) Have had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of paragraph (a)(1) of this section;

(C) Have a minimum of 60 hours of documented medical education in mammography, which shall include: Instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be category I and at least 15 of the category I hours shall have been acquired within the 3 years immediately prior to the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category I continuing medical education credits and will be accepted if documented in writing by the appropriate

representative of the training institution; and

(D) Unless the exemption in paragraph (a)(1)(iii)(B) of this section applies, have interpreted or multi-read at least 240 mammographic examinations within the 6-month period immediately prior to the date that the physician qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician.

(ii) Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

(A) Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in-between the two. The facility will choose one of these dates to determine the 24-month period.

(B) Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have taught or completed at least 15 category I continuing medical education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period. This training shall include at least six category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice; and

(C) Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the interpreting physician shall have at least 8 hours of training in the new mammographic modality.

(D) Units earned through teaching a specific course can be counted only once towards the 15 required by paragraph (a)(1)(ii)(B) of this section, even if the course is taught multiple times during the previous 36 months.

(iii) Exemptions. (A) Those physicians who qualified as interpreting physicians under paragraph (a)(1) of this section of FDA's interim regulations prior to April 28, 1999 are considered to have met the initial requirements of paragraph (a)(1)(i) of this section. They may continue to interpret mammograms provided they continue to meet the licensure requirement of paragraph (a)(1)(i)(A) of this section and the continuing experience and education requirements of paragraph (a)(1)(ii) of this section.

(B) Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any 6-month period during the last 2 years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from paragraph (a)(1)(i)(D) of this section.

(iv) Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall reestablish their qualifications before resuming the independent interpretation of mammograms, as follows:

(A) Interpreting physicians who fail to meet the continuing experience requirements of paragraph (a)(1)(ii)(A) of this section shall:

(*1*) Interpret or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician, or

(*2*) Interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician's total up to 960 examinations for the prior 24 months, whichever is less.

(*3*) The interpretations required under paragraph (a)(1)(iv)(A)(*1*) or (a)(1)(iv)(A)(*2*) of this section shall be done within the 6 months immediately prior to resuming independent interpretation.

(B) Interpreting physicians who fail to meet the continuing education requirements of paragraph (a)(1)(ii)(B) of this section shall obtain a sufficient number of additional category I continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

(2) Radiologic technologists. All mammographic examinations shall be performed by radiologic technologists who meet the following general requirements, mammography requirements, and continuing education and experience requirements:

(i) General requirements. (A) Be licensed to perform general radiographic procedures in a State; or

(B) Have general certification from one of the bodies determined by FDA to have procedures and requirements adequate to ensure that radiologic technologists certified by the body are competent to perform radiologic examinations; and

(ii) Mammography requirements. Have, prior to April 28, 1999 qualified as a radiologic technologist under paragraph (a)(2) of this section or completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:

(A) Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants;

(B) The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under paragraph (a)(2) of this section; and

(C) At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography exams; and

(iii) Continuing education requirements. (A) Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period.

(B) Units earned through teaching a specific course can be counted only once towards the 15 required in paragraph (a)(2)(iii)(A) of this section, even if the course is taught multiple times during the previous 36 months.

(C) At least six of the continuing education units required in paragraph (a)(2)(iii)(A) of this section shall be related to each mammographic modality used by the technologist.

(D) Requalification. Radiologic technologists who fail to meet the continuing education requirements of paragraph (a)(2)(iii)(A) of this section shall obtain a sufficient number of

continuing education units in mammography to bring their total up to at least 15 in the previous 3 years, at least 6 of which shall be related to each modality used by the technologist in mammography. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

(E) Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under paragraph (a)(2)(ii)(C) of this section, the technologist shall have at least 8 hours of continuing education units in the new modality.

(iv) Continuing experience requirements. (A) Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed or of October 28, 1997 whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter or any date in between the two. The facility will choose one of these dates to determine the 24-month period.

(B) Requalification. Radiologic technologists who fail to meet the continuing experience requirements of paragraph (a)(2)(iv)(A) of this section shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist, before resuming the performance of unsupervised mammography examinations.

(3) *Medical physicists.* All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under paragraph (e) of this section shall meet the following:

(i) Initial qualifications. (A) Be State licensed or approved or have certification in an appropriate specialty area by one of the bodies determined by FDA to have procedures and requirements to ensure that medical physicists certified by the body are competent to perform physics survey; and

(B)(*1*) Have a masters degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or equivalent (e.g., 30 quarter hours) of college undergraduate or graduate level physics;

(*2*) Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and

(*3*) Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999 experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of paragraphs (a)(3)(i) and (a)(3)(iii) of this section; or

(ii) Alternative initial qualifications. (A) Have qualified as a medical physicist under paragraph (a)(3) of this section of FDA's interim regulations and retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and

(B) Prior to the April 28, 1999 have:

(*1*) A bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics,

(*2*) Forty contact hours of documented specialized training in conducting surveys of mammography facilities and,

(*3*) Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements must be met after fulfilling the degree requirement.

(iii) Continuing qualifications. (A) Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. This continuing education shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.

(B) Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed or of October 28, 1997 whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least six mammography units during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter or any date in-between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period on a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

(C) Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under paragraph (a)(3)(i) or (a)(3)(ii) of this section, the physicist must receive at least 8 hours of training in surveying units of the new mammographic modality.

(iv) Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of paragraph (a)(3)(iii) of this section may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists must reestablish their qualifications, as follows:

(A) Medical physicists who fail to meet the continuing educational requirements of paragraph (a)(3)(iii)(A) of this section shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous 3 years.

(B) Medical physicists who fail to meet the continuing experience requirement of paragraph (a)(3)(iii)(B) of this section shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of paragraphs (a)(3)(i) and (a)(3)(iii) of this section to bring their total surveys up to the required two facilities and six units in the previous 24 months. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

(4) *Retention of personnel records.* Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the MQSA personnel requirements.

(b) *Equipment.* Regulations published under §§ 1020.30, 1020.31, and 900.12(e) of this chapter that are relevant to equipment performance should also be consulted for a more complete understanding of the equipment performance requirements.

(1) *Prohibited equipment.* Radiographic equipment designed for general purpose or special nonmammography procedures shall not be used for mammography. This prohibition includes systems that have been modified or equipped with special attachments for mammography. This requirement supersedes the implied acceptance of such systems in § 1020.31(f)(3) of this chapter.

(2) *General.* All radiographic equipment used for mammography shall be specifically designed for mammography and shall be certified pursuant to § 1010.2 of this chapter as meeting the applicable requirements of §§ 1020.30 and 1020.31 of this chapter in effect at the date of manufacture.

(3) *Motion of tube-image receptor assembly.* (i) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.

(ii) The mechanism ensuring compliance with paragraph (b)(3)(i) of this section shall not fail in the event of power interruption.

(4) *Image receptor sizes.* (i) Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 centimeters (cm) and 24 x 30 cm.

(ii) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

(iii) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

(5) *Beam limitation and light fields.* (i) All systems shall have beam-limiting devices that allow the useful beam to extend to or beyond the chest wall edge of the image receptor.

(ii) For any mammography system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

(6) *Magnification.* (i) Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator.

(ii) Systems used for magnification procedures shall provide, at a minimum, at least one magnification valve within the range of 1.4 to 2.0.

(7) *Focal spot selection.* (i) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(ii) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(iii) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.

(8) *Compression.* All mammography systems shall incorporate a compression device.

(i) Application of compression. Effective October 28, 1999 each system shall provide:

(A) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

(B) Fine adjustment compression controls operable from both sides of the patient.

(ii) Compression paddle. (A) Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for ''spot compression'') may be provided. Such compression paddles for special purposes are not subject to the requirements of paragraphs (b)(8)(ii)(D) and (b)(8)(ii)(E) of this section.

(B) Except as provided in paragraph (b)(8)(ii)(C) of this section, the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

(C) Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

(D) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(E) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

(9) *Technique factor selection and display.* (i) Manual selection of milliampere seconds (mAs) or at least one of its component parts (milliapere (mA) and/or time) shall be available.

(ii) The technique factors (peak tube potential in kilovolt (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls (AEC) are used, in which case the technique factors that are set prior to the exposure shall be indicated.

(iii) Following AEC mode use, the system shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure. The mAs may be displayed as mA and time.

(10) *Automatic exposure control.* (i) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(ii) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

(A) The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.

(B) The selected position of the detector shall be clearly indicated.

(iii) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

(11) *X-ray film.* The facility shall use X-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.

(12) *Intensifying screens.* The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.

(13) *Film processing solutions.* For processing mammography films, the facility shall use chemical solutions that

are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.

(14) *Lighting.* The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.

(15) *Film masking devices.* Facilities shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.

(c) *Medical records and mammography reports*—(1) *Contents and terminology.* Each facility shall prepare a written report of the results of each mammography examination performed under its certificate. The mammography report shall include the following information:

(i) The name of the patient and an additional patient identifier;

(ii) Date of examination;

(iii) The name of the interpreting physician who interpreted the mammogram;

(iv) Overall final assessment of findings, classified in one of the following categories:

(A) ''Negative:'' Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);

(B) ''Benign:'' Also a negative assessment;

(C) ''Probably Benign:'' Finding(s) has a high probability of being benign;

(D) ''Suspicious:'' Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;

(E) ''Highly suggestive of malignancy:'' Finding(s) has a high probability of being malignant;

(v) In cases where no final assessment category can be assigned due to incomplete work-up, ''Incomplete: Need additional imaging evaluation'' shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and

(vi) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

(2) *Communication of mammography results to the patient.* Each facility shall maintain a system to ensure that the results of each mammographic examination are communicated to the patient in a timely manner. If assessments are ''Suspicious'' or ''Highly suggestive of malignancy'' and the patient has not named a health care provider, the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(i) As soon as possible, but no later than 30 days from the date of the mammography examination, patients who do not name a health care provider to receive the mammography report shall be sent the report described in paragraph (c)(1) of this section, in addition to a written notification of results in lay terms.

(ii) Each facility that accepts patients who do not have a primary care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

(3) *Communication of mammography results to health care providers.* When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

(i) Provide a written report of the mammography examination, including the items listed in paragraph (c)(1) of this section, to that health care provider as soon as possible, but no later than 30 days from the date of the mammography examination; and

(ii) If the assessment is ''Suspicious'' or ''Highly suggestive of malignancy,'' make reasonable attempts to communicate with the health care provider as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.

(4) *Recordkeeping.* Each facility that performs mammograms:

(i) Shall (except as provided in paragraph (c)(3)(ii) of this section) maintain mammography films and reports in a permanent medical record of the patient for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility, or a longer period if mandated by State or local law; and

(ii) Shall upon request or on behalf of, by the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly;

(iii) Any fee charged to the patients for providing the services in paragraph (c)(4)(ii) of this section shall not exceed the documented costs associated with this service.

(5) *Mammographic image identification.* Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(i) Name of patient and an additional patient identifier.

(ii) Date of examination.

(iii) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by FDA in accordance with § 900.3(b) or § 900.4(a)(8) shall be used to identify view and laterality.

(iv) Facility name and location. At a minimum, the location shall include the city, State, and zip code of the facility.

(v) Technologist identification.

(vi) Cassette/screen identification.

(vii) Mammography unit identification, if there is more than one unit in the facility.

(d) *Quality assurance—general.* Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility.

(1) *Responsible individuals.* Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

(i) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of paragraphs (d) through (f) of this section. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

(ii) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:

(A) Follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and

(B) Participate in the facility's medical outcomes audit program.

(iii) Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment

evaluations and providing the facility with the reports described in paragraphs (e)(9) and (e)(10) of this section.

(iv) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of paragraph (e) of this section.

(2) *Quality assurance records.* The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, and protection are properly maintained and updated. These quality control records shall be kept for each test specified in paragraphs (e) and (f) of this section until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

(e) *Quality assurance—equipment*—(1) *Daily quality control tests.* Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that examinations are performed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

(i) The base plus fog density shall be within + 0.03 of the established operating level.

(ii) The mid-density shall be within + 0.15 of the established operating level.

(iii) The density difference shall be within + 0.15 of the established operating level.

(2) *Weekly quality control tests.* Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

(i) The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.

(ii) The optical density of the film at the center of the phantom image shall not change by more than + 0.20 from the established operating level.

(iii) The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by FDA in accordance with § 900.3(d) or § 900.4(a)(8).

(iv) The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than ± 0.05 from the established operating level.

(3) *Quarterly quality control tests.* Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

(i) Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square cm.

(ii) Repeat analysis. If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

(4) *Semiannual quality control tests.* Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

(i) Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

(ii) Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

(iii) Compression device performance. (A) A compression force of at least 111 newtons (25 pounds) shall be provided.

(B) Effective October 28, 1999 the maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and 209 newtons (47 pounds).

(5) Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

(i) Automatic exposure control performance. (A) The AEC shall be capable of maintaining film optical density within ± 0.30 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within ± 0.30 of the average under phototimed conditions can be produced.

(B) After October 28, 1999 the AEC shall be capable of maintaining film optical density (OD) within ± 0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

(C) The optical density of the film in the center of the phantom image shall not be less than 1.20.

(ii) Kilovoltage peak (kVp) accuracy and reproducibility. (A) The kVp shall be accurate within + 5 percent of the indicated or selected kVp at:

(*1*) The lowest clinical kVp that can be measured by a kVp test device;

(*2*) The most commonly used clinical kVp;

(*3*) The highest available clinical kVp, and

(B) At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

(iii) Focal spot condition. Until October 28, 1999 focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. After October 28, 1999 facilities shall evaluate focal spot condition only by determining the system resolution.

(A) System Resolution. (*1*) Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 Cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.

(*2*) The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall

edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.

(*3*) When more than one target material is provided, the measurement in paragraph (e)(5)(iii)(A) of this section shall be made using the appropriate focal spot for each target material.

(*4*) When more than one SID is provided, the test shall be performed at SID most commonly used clinically.

(*5*) Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

(B) Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified in Table 1.

TABLE 1

| Focal Spot Tolerance Limit | | |
|---|---|---|
| Nominal Focal Spot Size (mm) | Maximum Measured Dimensions | |
| | Width(mm) | Length(mm) |
| 0.10 | 0.15 | 0.15 |
| 0.15 | 0.23 | 0.23 |
| 0.20 | 0.30 | 0.30 |
| 0.30 | 0.45 | 0.65 |
| 0.40 | 0.60 | 0.85 |
| 0.60 | 0.90 | 1.30 |

(iv) Beam quality and half-value layer (HVL). The HVL shall meet the specifications of § 1020.30(m)(1) of this chapter for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.

TABLE 2

| X-ray Tube Voltage (kilovolt peak) and Minimum HVL | | |
|---|---|---|
| Designed Operating Range (kV) | Measured Operating Voltage (kV) | Minimum HVL (millimeters of aluminum) |
| Below 50 | 20 | 0.20 |
| | 25 | 0.25 |
| | 30 | 0.30 |

(v) Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

(vi) Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

(vii) X-ray field/light field/image receptor/compression paddle alignment. (A) All systems shall have beam-limiting devices that allow the useful X-ray beam to extend to or beyond the edges of the image receptor but by no more than 2 percent of the SID at the chest wall side.

(B) If a light field that passes through the X-ray beam limitation device is provided, it shall be aligned with the X-ray field so that the total of any misalignment of the edges of the light field and the X-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2 percent of the SID.

(C) The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than one percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.

(viii) Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

(ix) System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

(x) Radiation output. (A) The system shall be capable of producing a minimum output of 4.5 mGy air kerma per second (513 milli Roentgen (mR) per second) when operating at 28 kVp in the standard mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 1999 the system, under the same measuring conditions shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 mR per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate.

(B) The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

(xi) Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

(A) An override capability to allow maintenance of compression;

(B) A continuous display of the override status; and

(C) A manual emergency compression release that can be activated in the event of power or automatic release failure.

(6) *Quality control tests—other modalities.* For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.

(7) *Mobile Units.* The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in paragraphs (e)(1) through (e)(6) of this section. In addition, at each examination location, before any examinations are conducted, the facility shall verify satisfactory performance of such units using a test method that establishes the adequacy of the image quality produced by the unit.

(8) *Use of test results.* (i) After completion of the tests specified in paragraphs (e)(1) through (e)(7) of this section, the facility shall compare the test results to the corresponding specified action limits; or, for nonscreen-film modalities, to the manufacturer's recommended action limits; or, for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.

(ii) If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further examinations are performed or any films are processed using the component of the mammography system that failed the test, if the failed test was that described in paragraphs (e)(1), (e)(2), (e)(4)(ii), (e)(4)(iii), (e)(5)(i), (e)(5)(iii), (e)(5)(v), (e)(5)(vi), (e)(6), or (e)(7) of this section;

(B) Within 30 days of the test date for all other tests described in paragraph (e) of this section.

(9) *Surveys.* (i) At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in paragraphs (e)(5) and (e)(6) of this section and the weekly phantom image quality test described in paragraph (e)(2) of this section.

(ii) The results of all tests conducted by the facility in accordance with paragraphs (e)(1) through (e)(7) of this section, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.

(iii) The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

(iv) The survey report shall be sent to the facility within 30 days of the date of the survey.

(v) The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

(10) *Mammography equipment evaluations.* Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is dissembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

(11) *Facility cleanliness.* (i) The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness.

(ii) The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

(12) *Calibration of air kerma measuring instruments.* Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every 2 years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of + 6 percent (95 percent confidence level) in the mammography energy range.

(13) *Infection control.* Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

(i) Comply with all applicable Federal, State, and local regulations pertaining to infection control; and

(ii) Comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or

(iii) If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

(f) *Quality assurance-mammography medical outcomes audit.* Each facility shall establish and maintain a mammography medical outcomes audit program to followup positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) *General requirements.* Each facility shall establish a system to collect and review outcome data for all mammograms performed, including followup on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate followup on surgical and/or pathology results and review of the

mammograms taken prior to the diagnosis of a malignancy.

(2) *Frequency of audit analysis.* The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified, or 12 months after April 28, 1999 whichever date is the latest. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

(3) *Reviewing interpreting physician.* Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results, notifying other interpreting physicians of their results and the facility aggregate results. If followup actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the followup.

(g) *Mammographic procedure and techniques for mammography of patients with breast implants.* (1) Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic exam.

(2) Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.

(h) *Consumer compliant mechanism.* Each facility shall:

(1) Establish a written and documented system for collecting and resolving consumer complaints;

(2) Maintain a record of each serious complaint received by the facility for at least 3 years from the date the complaint was received;

(3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body if the facility is unable to resolve a serious complaint to the consumer's satisfaction;

(4) Report unresolved serious complaints to the accreditation body in a manner and timeframe specified by the accreditation body.

(i) *Clinical image quality.* Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

(j) *Additional mammography review and patient notification.* (1) If FDA believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by FDA, for review by the accreditation body or other entity designated by FDA. This additional mammography review will help the agency to determine whether the facility is in compliance with this section and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

(2) If FDA determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a timeframe and in a manner specified by FDA.

**§ 900.13 Revocation of accreditation and revocation ofaccreditation body approval.**

(a) *FDA action following revocation of accreditation.* If a facility's accreditation is revoked by an accreditation body, the agency may conduct an investigation into the reasons for the revocation. Following such investigation, the agency may determine that the facility's certificate shall no longer be in effect or the agency may take whatever other action or combination of actions will best protect the public health, including the establishment and implementation of a corrective plan of action that will permit the certificate to continue in effect while the facility seeks reaccreditation. A facility whose certificate is no longer in effect because it has lost its accreditation may not practice mammography.

(b) *Withdrawal of FDA approval of an accreditation body.* (1) If FDA withdraws approval of an accreditation body under § 900.6, the certificates of facilities previously accredited by such body shall remain in effect for up to 1 year from the date of the withdrawal of approval, unless FDA determines, in order to protect human health or because the accreditation body fraudulently accredited facilities, that the certificates of some or all of the facilities should be revoked or suspended or that a shorter time period should be established for the certificates to remain in effect.

(2) After 1 year from the date of withdrawal of approval of an accreditation body, or within any shorter period of time established by the agency, the affected facilities must obtain accreditation from another accreditation body, or from another entity designated by FDA.

**§ 900.14 Suspension or revocation of certificates.**

(a) Except as provided in paragraph (b) of this section, FDA may suspend or revoke a certificate if FDA finds, after providing the owner or operator of the facility with notice and opportunity for an informal hearing in accordance with part 16 of this chapter, that the owner, operator, or any employee of the facility:

(1) Has been guilty of misrepresentation in obtaining the certificate;

(2) Has failed to comply with the standards of § 900.12;

(3) Has failed to comply with reasonable requests of the agency or the accreditation body for records, information, reports, or materials that FDA believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of § 900.12;

(4) Has refused a reasonable request of a duly designated FDA inspector, State inspector, or accreditation body representative for permission to inspect the facility or the operations and pertinent records of the facility;

(5) Has violated or aided and abetted in the violation of any provision of or regulation promulgated pursuant to 42 U.S.C. 263b; or

(6) Has failed to comply with prior sanctions imposed by the agency under 42 U.S.C. 263b(h).

(b) FDA may suspend the certificate of a facility before holding a hearing if FDA makes a finding described in paragraph (a) of this section and also determines that;

(1) The failure to comply with required standards presents a serious risk to human health;

(2) The refusal to permit inspection makes immediate suspension necessary; or

(3) There is reason to believe that the violation or aiding and abetting of the violation was intentional or associated with fraud.

(c) If FDA suspends a certificate in accordance with paragraph (b) of this section:

(1) The agency shall provide the facility with an opportunity for an informal hearing under part 16 of this chapter not later than 60 days from the effective date of this suspension;

(2) The suspension shall remain in effect until the agency determines that:

(i) Allegations of violations or misconduct were not substantiated;

(ii) Violations of required standards have been corrected to the agency's satisfaction; or

(iii) The facility's certificate is revoked in accordance with paragraph (d) of this section;

(d) After providing a hearing in accordance with paragraph (c)(1) of this section, the agency may revoke the facility's certificate if the agency determines that the facility:

(1) Is unwilling or unable to correct violations that were the basis for suspension; or

(2) Has engaged in fraudulent activity to obtain or continue certification.

**§ 900.15 Appeals of adverse accreditation or reaccreditation decisions that preclude certification or recertification.**

(a) The appeals procedures described in this section are available only for adverse accreditation or reaccreditation decisions that preclude certification or recertification by FDA. Agency decisions to suspend or revoke certificates that are already in effect will be handled in accordance with § 900.14.

(b) Upon learning that a facility has failed to become accredited or reaccredited, FDA will notify the facility that the agency is unable to certify that facility without proof of accreditation.

(c) A facility that has been denied accreditation or reaccreditation is entitled to an appeals process from the accreditation body, in accordance with § 900.7. A facility must avail itself of the accreditation body's appeal process before requesting reconsideration from FDA.

(d) A facility that cannot achieve satisfactory resolution of an adverse accreditation decision through the accreditation body's appeal process is entitled to further appeal in accordance with procedures set forth in this section and in regulations published in 42 CFR part 498.

(1) References to the Health Care Financing Administration (HCFA) in 42 CFR part 498 should be read as the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiological Health, Food and Drug Administration.

(2) References to the Appeals Council of the Social Security Administration in 42 CFR part 498 should be read as references to the Departmental Appeals Board.

(3) In accordance with the procedures set forth in subpart B of 42 CFR part 498, a facility that has been denied accreditation following appeal to the accreditation body may request reconsideration of that adverse decision from DMQRP.

(i) A facility must request reconsideration by DMQRP within 60 days of the accreditation body's adverse appeals decision, at the following address: Division of Mammography Quality and Radiation Programs (HFZ–240), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, Attn: Facility Accreditation Review Committee.

(ii) The request for reconsideration shall include three copies of the following records:

(A) The accreditation body's original denial of accreditation.

(B) All information the facility submitted to the accreditation body as part of the appeals process;

(C) A copy of the accreditation body's adverse appeals decision; and

(D) A statement of the basis for the facility's disagreement with the accreditation body's decision.

(iii) DMQRP will conduct its reconsideration in accordance with the procedures set forth in subpart B of 42 CFR part 498.

(4) A facility that is dissatisfied with DMQRP's decision following reconsideration is entitled to a formal hearing in accordance with procedures set forth in subpart D of 42 CFR part 498.

(5) Either the facility or FDA may request review of the hearing officer's decision. Such review will be conducted by the Departmental Appeals Board in accordance with subpart E of 42 CFR part 498.

(6) A facility cannot perform mammography services while an adverse accreditation decision is being appealed.

**§ 900.16 Appeals of denials of certification.**

(a) The appeals procedures described in this section are available only to facilities that are denied certification by FDA after they have been accredited by an approved accreditation body. Appeals for facilities that have failed to become accredited are governed by the procedures set forth in § 900.15.

(b) FDA may deny the application if the agency has reason to believe that:

(1) The facility will not be operated in accordance with standards established under § 900.12;

(2) The facility will not permit inspections or provide access to records or information in a timely fashion; or

(3) The facility has been guilty of misrepresentation in obtaining the accreditation.

(c)(1) If FDA denies an application for certification by a faciity that has received accreditation from an approved accreditation body, FDA shall provide the facility with a statement of the grounds on which the denial is based.

(2) A facility that has been denied accreditation may request reconsideration and appeal of FDA's determination in accordance with the applicable provisions of § 900.15(d).

**§ 900.17 [Reserved]**

**§ 900.18 Alternative requirements for § 900.12 quality standards.**

(a) *Criteria for approval of alternative standards.* Upon application by a qualified party as defined in paragraph (b) of this section, FDA may approve an alternative to a quality standard under § 900.12, when the agency determines that:

(1) The proposed alternative standard will be at least as effective in assuing quality mammography as the standard it proposes to replace, and

(2) The proposed alternative:

(i) Is too limited in its applicability to justify an amendment to the standard; or

(ii) Offers an expected benefit to human health that is so great that the time required for amending the standard would present an unjustifiable risk to the human health; and

(3) The granting of the alternative is in keeping with the purposes of 42 U.S.C. 263b.

(b) *Applicants for alternatives.* (1) Mammography facilities and accreditation bodies may apply for alternatives to the quality standards of § 900.12.

(2) Federal agencies and State governments that are not accreditation bodies may apply for alternatives to the standards of § 900.12(a).

(3) Manufacturers and assemblers of equipment used for mammography may apply for alternatives to the standards of § 900.12(b) and (e).

(c) *Applications for approval of an alternative standard.* An application for approval of an alternative standard or for an amendment or extension of the alternative standard shall be submitted in an original and two copies to the Director, Division of Mammography Quality and Radiation Programs (HFZ–240), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. The application for approval of an alternative standard shall include the following information:

(1) Identification of the original standard for which the alternative standard is being proposed and an explanation of why the applicant is proposing the alternative;

(2) A description of the manner in which the alternative is proposed to deviate from the original standard;

(3) A description, supported by data, of the advantages to be derived from such deviation;

(4) An explanation, supported by data, of how such a deviation would ensure equal or greater quality of production, processing, or interpretation of mammograms than the original standard;

(5) The suggested period of time that the proposed alternative standard would be in effect; and

(6) Such other information required by the Director to evaluate and act on the application.

(d) *Ruling on applications.* (1) FDA may approve or deny, in whole or in part, a request for approval of an alternative standard or any amendment or extension thereof, and shall inform the applicant in writing of this action. The written notice shall state the manner in which the requested alternative standard differs from the agency standard and a summary of the reasons for approval or denial of the request. If the request is approved, the written notice shall also include the effective date and the termination date of the approval and a summary of the limitations and conditions attached to the approval and any other information that may be relevant to the approved request. Each approved alternative standard shall be assigned an identifying number.

(2) Notice of an approved request for an alternative standard or any amendment or extension thereof shall be placed in the public docket file in the Dockets Management Branch and may also be in the form of a notice published in the **Federal Register**. The notice shall state the name of the applicant, a description of the published agency standard, and a description of the approved alternative standard, including limitations and conditions attached to the approval of the alternative standard.

(3) Summaries of the approval of alternative standards, including information on their nature and number, shall be provided to the National Mammography Quality Assurance Advisory Committee.

(4) All applications for approval of alternative standards and for amendments and extensions thereof and all correspondence (including written notices of approval) on these applications shall be available for public disclosure in the Dockets Management Branch, excluding patient identifiers and confidential commercial information.

(e) *Amendment or extension of an alternative standard.* An application for amending or extending approval of an alternative standard shall include the following information:

(1) The approval number and the expiration date of the alternative standard;

(2) The amendment or extension requested and the basis for the amendment or extension; and

(3) An explanation, supported by data, of how such an amendment or extension would ensure equal or greater quality of production, processing, or interpretation of mammograms than the original standard.

(f) *Applicability of the alternative standards.* (1) Except as provided in paragraphs (f)(2) and (f)(3) of this section, any approval of an alternative standard, amendment, or extension may be implemented only by the entity to which it was granted and under the terms under which it was granted. Other entities interested in similar or identical approvals must file their own application following the procedures of paragraph (c) of this section.

(2) When an alternative standard is approved for a manufacturer of equipment, any facility using that equipment will also be covered by the alternative standard.

(3) The agency may extend the alternative standard to other entities when FDA determines that expansion of the approval of the alternative standard would be an effective means of promoting the acceptance of measures to improve the quality of mammography. All such determinations will be publicized by appropriate means.

(g) *Withdrawal of approval of alternative requirements.* FDA shall amend or withdraw approval of an alternative standard whenever the agency determines that this action is necessary to protect the human health or otherwise is justified by § 900.12. Such action will become effective on the date specified in the written notice of the action sent to the applicant, except that it will become effective immediately upon notification of the applicant when FDA determines that such action is necessary to prevent an imminent health hazard.

Dated: September 25, 1997.

**Michael A. Friedman,**

*Lead Deputy Commissioner for the Food and Drug Administration.*

**Donna E. Shalala,**

*Secretary of Health and Human Services.*

[FR Doc. 97–26351 Filed 10–27–97; 8:45 am]

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federal register

Tuesday
October 28, 1997

# Part III

# Department of Agriculture

## Food Safety and Inspection Service

**9 CFR Chapter III, et al.**

**Retraction of an Announcement Concerning Nonfood Compounds and Proprietary Substances; Final Rule and Sanitation Requirements for Official Meat and Poultry Establishments; Comment Period Reopening; Proposed Rule**

## DEPARTMENT OF AGRICULTURE

## Food and Safety and Inspection Service

## 9 CFR Chapter III

**[Docket No. 97–062N]**

## Retraction of an Announcement Concerning Nonfood Compounds and Proprietary Substances

**AGENCY:** Food and Safety Inspection Service, USDA.

**ACTION:** Policy statement.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is issuing a retraction of an announcement that was mailed to chemical manufacturers and other businesses and posted on the FSIS Internet site. This announcement incorrectly stated that FSIS is discontinuing its policy of approving all nonfood compounds and proprietary substances prior to their use in official meat and poultry establishments. Although FSIS did recently publish a proposal to revise its sanitation regulations, some of which govern the use of certain nonfood compounds, the Agency has not proposed to revise its policy of approving all nonfood compounds or proprietary substances prior to their use in official establishments.

**FOR FURTHER INFORMATION CONTACT:** Patricia F. Stolfa, Assistant Deputy Administrator, Regulations and Inspection Methods, Food Safety and Inspection Service, U.S. Department of Agriculture (202) 205–0699.

**SUPPLEMENTARY INFORMATION:**

### Background

On September 11, 1997, the FSIS Compound and Packaging Review Branch mailed a notice to chemical manufacturers and other businesses announcing a change of address. Included with that notice was a facsimile of the first page of a proposed rule, incorrectly identified as FSIS Docket No. 96–037P, announcing that the Agency was discontinuing its policy of approving all nonfood compounds and proprietary substances prior to their use in official meat and poultry establishments. Around the same time, this facsimile also was posted on the FSIS Internet site. There is, in fact, no such proposed rule.

On August 25, 1997, FSIS published a proposal to convert to performance standards the sanitation requirements for meat and poultry establishments (FSIS Docket No. 96–037P; ''Sanitation Requirements for Official Meat and Poultry Establishments''; 62 FR 45045). In this document, FSIS proposed to eliminate the regulations requiring that certain nonfood compounds, such as sanitizers and pesticides, be approved by the Agency prior to their use in official establishments. FSIS did not propose, however, to discontinue its policy of approving all other nonfood compounds or proprietary substances prior to their use in official establishments.

FSIS is currently considering how to proceed in regard to its policy of preapproving nonfood compounds and proprietary substances. In general, prior approval requirements are inconsistent with the Agency's recently finalized HACCP requirements. FSIS will publish in the **Federal Register** a notice explaining any future revisions to its prior approval policy for nonfood compounds and proprietary substances.

FSIS is in the process of directly notifying each business that may have been mailed the inaccurate notice of proposed rulemaking in order to clarify the Agency's current policy in regard to nonfood compounds and proprietary substances. FSIS is publishing this retraction to clarify its policy for other businesses and individuals. Also, in order to address any confusion regarding the published sanitation proposal, FSIS is reopening the comment period for that proposal elsewhere in this issue of the **Federal Register** (FSIS Docket No. 96–037R, ''Sanitation Requirements for Official Meat and Poultry Establishments; Comment Period Reopening'').

Done in Washington, DC: October 22, 1997.

**Thomas J. Billy,**

*Administrator, Food Safety Inspection Service.*

[FR Doc. 97–28429 Filed 10–22–97; 4:50 pm]

BILLING CODE 3410–DM–M

**DEPARTMENT OF AGRICULTURE**

**Food Safety and Inspection Service**

**9 CFR Parts 303, 308, 381, and 416**

**[Docket No. 96–037R]**

## Sanitation Requirements for Official Meat and Poultry Establishments; Comment Period Reopening

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Proposed rule; reopening of comment period.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is reopening the comment period for its proposal to revise the regulatory requirements concerning sanitation in official meat and poultry establishments (FSIS Docket No. 96–037P; ''Sanitation Requirements for Official Meat and Poultry Establishments''). The comment period closing date for that proposal will now be Monday, November 10, 1997.

**DATES:** Comments must be received on or before November 10, 1997.

**ADDRESSES:** Submit one original and two copies of written comments to FSIS Docket Clerk, Docket #96–037P, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th St. SW., Washington, DC 20250–3700. All comments submitted in response to this proposal will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 4;30 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Patricia F. Stolfa, Assistant Deputy Administrator, Regulations and Inspection Methods, Food Safety and Inspection Service, U.S. Department of Agriculture, (202) 205–0699.

**SUPPLEMENTARY INFORMATION:**

### Background

The Food Safety and Inspection Service (FSIS) is reopening the comment period for its proposal ''Sanitation Requirements for Official Meat and Poultry Establishments'' (FSIS Docket No. 96–037P; 62 FR 45045, August 25, 1997). Shortly after the comment period for that proposal opened, FSIS released information that mischaracterized the provisions concerning the use of nonfood compounds. In order to alleviate any confusion regarding the sanitation proposal and to clarify FSIS policy in regard to nonfood compounds, FSIS is publishing, elsewhere in this issue of the **Federal Register**, a retraction of the erroneous information (FSIS Docket No. 97–062N, ''Retraction of an Announcement Concerning Nonfood Compounds and Proprietary Substances''). In order to ensure that the public has ample opportunity to submit meaningful comments on the proposal to revise the sanitation regulations, FSIS is reopening the comment period for that proposal.

Done in Washington, DC: October 22, 1997.

**Thomas J. Billy,**

*Administrator, Food Safety Inspection Service.*

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Tuesday
October 28, 1997

# Part IV

# Department of Agriculture

## Animal and Plant Health Inspection Service

**9 CFR Parts 92, 93, 94, 95, 96, 97, 98, and 130**

**Importation of Animals and Animal Products; APHIS Policy Regarding Importation of Animals and Animal Products; Final Rule and Notice**

**DEPARTMENT OF AGRICULTURE**

**Animal and Plant Health Inspection Service**

**9 CFR Parts 92, 93, 94, 95, 96, 97, 98, and 130**

**[Docket No. 94–106–9]**

**RIN 0579–AA71**

# Importation of Animals and Animal Products

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** We are establishing procedures for recognizing regions, rather than only countries, for the purpose of the importation of animals and animal products into the United States. We are also establishing procedures by which regions may request permission to export animals and animal products to the United States under specified conditions, based on the regions' disease status. These changes to the regulations are in accordance with international trade agreements entered into by the United States. We are also allowing, under certain conditions, the unloading and reloading at the port of arrival of meat and other animal products otherwise prohibited entry into the United States. This change is warranted because it removes unnecessary restrictions on the transiting of meat and other animal products through the United States, without increasing the likelihood that the meat or other products will introduce diseases of livestock or poultry. Additionally, we are removing the requirement that cattle from Canada be tested for brucellosis before being imported into the United States. This change is warranted because the risk that cattle imported from Canada will be infected with brucellosis is slight. We are also making other minor changes in our requirements for importing animals and animal products that will relieve some import restrictions while continuing to protect U.S. livestock and poultry from foreign animal diseases.

**EFFECTIVE DATE:** November 28, 1997.

**FOR FURTHER INFORMATION CONTACT:** Dr. Gary Colgrove, Chief Staff Veterinarian, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231, (301) 734–8590.

**SUPPLEMENTARY INFORMATION:**

## Background

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), has promulgated regulations regarding the importation of animals and animal products in order to guard against the introduction into the United States of animal diseases not currently present or prevalent in this country. These regulations are set forth in the Code of Federal Regulations (CFR), title 9, chapter 1.

On April 18, 1996, we published in the **Federal Register** (61 FR 16978–17105, Docket No. 94–106–1) a proposed rule to revise the regulations in six different parts of 9 CFR, chapter I, to establish importation criteria for ruminants and swine, and their products, based on the level of disease risk in specified geographical regions.

We solicited comments concerning our proposal for 90 days ending July 17, 1996. During the comment period, several commenters requested that we extend the period during which we would accept comments. In response to these requests, on July 11, 1996, we published in the **Federal Register** a notice that we would consider comments on the proposed rule for an additional 60 days ending September 16, 1996 (61 FR 36520, Docket No. 94–106–4). During the comment period, we conducted four public hearings at which we accepted oral and written comments from the public. These public hearings were held in Riverdale, MD; Atlanta, GA; Kansas City, MO; and Denver, CO.

We received 113 comments on the proposed rule on or before September 16, 1996. These comments came from representatives of State and foreign governments, international economic and political organizations, veterinary associations, State departments of agriculture, livestock industry associations and other agricultural organizations, importing and exporting associations, members of academia and the research community, brokerage firms, exhibitors, animal welfare organizations, and other members of the public.

Based on our evaluation of the information submitted by commenters, we are making changes to the proposed rule in this final rule. We discuss below the issues raised by commenters and the changes we are making to the rule as proposed.

## What We Proposed

Broadly speaking, in the proposed rule, we set forth the following items regarding the importation of ruminants and swine, and their products:

- A list of restricted disease agents, including restricted disease vectors;
- Criteria for identifying regions;
- Criteria for classifying regions as to level of risk for specific disease agents;
- Procedures for applying for risk classification;
- Risk classifications for individual countries and other regions;
- Import conditions applicable to particular commodities from particular regions, based on the risk posed by specific diseases; and
- Changes in terminology throughout the ruminant and swine and ruminant and swine product import regulations to refer to ''regions'' rather than to countries.

We proposed to classify all countries of the world into one of six categories for each restricted disease agent. The six risk categories ranged from Risk Class RN (negligible risk), to Risk Class R1 (slight risk), Risk Class R2 (low risk), Risk Class R3 (moderate risk), Risk Class R4 (high risk), and Risk Class RU (unknown risk). We used what we termed ''qualitative criteria'' to assign risk categories—i.e., we examined certain pre-assigned criteria to determine what level of risk the importation of ruminants, swine, or their products from a particular region would present for a particular disease if no restrictions were placed on the importations. We also proposed, as an alternative to qualitative risk assessment, to allow potential exporting regions to demonstrate by means of a ''quantitative'' risk assessment that they should be assigned to a particular risk category because of a demonstrated quantitative risk of disease introduction due to unrestricted importation from that region.

Once we proposed to classify all countries of the world for each restricted disease agent (although the proposal allowed for regional status, in all cases but one we classified only countries, pending future requests for specific regions), we set forth the conditions each region assigned to a particular risk category would have to meet in order to import ruminants, swine, or their products into the United States. Under our proposal, all regions assigned to the same risk category for a particular disease and commodity would have been subject to the same import conditions.

### *Public Involvement in the Rulemaking Process*

A number of commenters requested that we extend the comment period during which comments would be accepted on the proposed rule. As noted above, we extended the initial 90-day comment period by 60 days to accommodate commenter requests. In addition, we accepted public comment

at four public hearings held in different areas of the United States. Therefore, we believe the public was given adequate time to comment on the proposed rule.

Some commenters recommended that the proposed rule be withdrawn, and a revised proposal be published following review and revision in consultation with groups outside the Animal and Plant Health Inspection Service (APHIS). Other commenters requested that APHIS hold meetings to explain the science that went into the proposal's development. Several commenter's recommended that the regulations provide for an open public hearing process to allow U.S. producers the opportunity to evaluate how APHIS will determine risk levels and the status of foreign animal health programs. One commenter recommended that APHIS take into account evaluations conducted by other countries, the International Office of Epizootics (OIE), and the European Union (EU). We believe that each of these requests for more public involvement in the process of regionalization and risk assessment is addressed by the changes we are making to the final rule, and by the policy we intend to follow regarding requests for regionalization. We discuss these rule changes and policy in this **SUPPLEMENTARY INFORMATION** below, under the heading ''APHIS Response to General Concerns.'' General Concerns with APHIS' Proposed Approach to Regionalization and Risk Assessment .

Although the proposal generated significant support from the public for the concepts of regionalization and levels of risk, a number of commenters expressed concern with the approach we proposed to take to implement those concepts.

The commenters who objected to our proposed approach focused on two broad areas: (1) The criteria, procedures, and risk classifications we proposed in assigning regions to one of the six risk categories; and (2) the conditions regions would have to meet, based on their risk classification, in order to export specific commodities. We discuss below first the broad objections to our proposed method of classifying regions, then the broad objections to the system of conditions that we proposed to apply to importations.

**Concerns Regarding Risk Classification Approach**

A number of commenters stated that the proposed rule would not be ''transparent'' to U.S. producers and to our trading partners, and that its complexity would cause it to be ineffective. These commenters expressed concern that the proposed six categories of risk would be too many to administer effectively. Some commenters recommended that APHIS simply amend the current import requirements to allow for recognition of regions, without incorporating provisions for classification by risk level.

A number of commenters stated that the use of scientific criteria is not evident in the proposed risk classifications of various countries/regions. Some commenters stated that the proposed regulations lacked transparency as to how evaluations of regions based on the qualitative risk criteria would be done. Other commenters stated that the risk categories did not take into account factors such as mode of transmission, economic consequences, zoonosis, and clustering of infected populations.

Some commenters questioned the validity of using arbitrarily selected prevalence thresholds for assigning risk categories. Some commenters questioned how what they termed ''information uncertainty'' would be dealt with.

A number of commenters stated that application for recognition of risk classification would demand an exhaustive process. Other commenters expressed concern that outbreaks of disease in restricted areas may not be readily regionalized.

**Concerns Regarding Proposed Import Conditions Based on Risk Classifications**

Some commenters objected to the specificity of the proposed import conditions, stating that the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO-SPS) states that a country must accept the sanitary measures imposed by other members as equivalent measures, even when they differ from those in the importing country, if the exporting member objectively demonstrates to the importing member that its actions provide the health protection required by the importing country. The commenters stated that the proposed import conditions did not adhere to this requirement.

Some commenters expressed concern that what they viewed as the ''rigidity'' of the proposed provisions would result in unnecessary difficulties in access to the U.S. market for commodities from acceptable exporting regions.

**APHIS Response to General Concerns**

When we drafted the proposed rule, our overriding goal was to create a mechanism for regionalized, risk-based import requirements, consistent with the obligations of the WTO-SPS Agreement, that would continue to protect livestock in the United States with the level of security provided by the current regulations. The principles of the WTO-SPS Agreement do require that SPS measures be equitably applied, scientifically sound, guided by international standards, transparent, taken in recognition that equal levels of risk mitigation can be achieved by applying differing sanitary measures, risk-assessment based, and applicable on a regional basis. If the principles of the WTO-SPS Agreement are fulfilled without discrimination and unjustified differences, nations may impose those sanitary requirements necessary to protect their livestock, poultry, wildlife, and human populations from disease.

We developed the proposed rule with the multiple aims of providing for regionalization, recognizing gradations of risk, and making it clear that we would impose identical import restrictions on regions with identical risk situations. In order to give potential importers advance notice of the type of import conditions they would face if they intended to import ruminants or swine, or their products, we included in the proposal a tentative risk classification for each country of the world for each restricted disease agent. Where current regulations existed regarding a particular country, commodity, and disease, our general approach was to apply the same import conditions applicable under the current regulations. Where the current regulations were silent on a restricted disease agent, we either assigned a Risk Class RU (unknown risk) classification to the country, or we tentatively assigned the country a risk classification based on the literature and other information available to us. The public was invited to comment on the proposed risk classifications.

There are many possible ways to categorize the varying levels of risk posed by different areas of the world for different diseases. Levels of risk can be described by a minimal number of categories, as under the current regulations (which recognize, generally, countries as ''free,'' ''free with restrictions (modified free),'' and ''not free''), or by an expansive spectrum of levels that recognizes extremely slight differences in risk among areas.

In developing the proposal, we arrived at the proposed number of risk classifications after a review of the continuum of possible risks, from negligible risk to unknown risk. One of the options we considered was proposing fewer than six risk

classifications. The six classifications we did propose represented a series of increasing risk situations, from what we considered to be a negligible risk, to slight risk, low risk, moderate risk, high risk, and unknown risk. It would have been possible to broadly divide the risk categories into ''low risk'' (to include the proposed classifications of negligible risk, slight risk, and low risk), ''high risk'' (to include the proposed classifications of moderate risk and high risk), and ''unknown risk.'' However, we rejected a three-category option, for the following reasons. First, under such an option, the ''high risk'' classification would not differentiate between a region affected with a high prevalence of a disease and a region that is affected with the disease but that has a strong control program and a low prevalence of infection. Grouping the classifications of moderate and high risk together would not have allowed for importations from regions that are at a low-prevalence level and are likely to remain so.

The three proposed risk classifications that could have been broadly grouped under ''low risk'' are also distinguishable. Of the countries considered ''free'' of certain diseases under the current regulations, some are subject to additional restrictions because they either supplement their national meat supply with fresh (chilled or frozen) meat from countries affected diseases of concern, share a common border with such countries, or have trading practices less restrictive than what we consider acceptable to prevent the introduction of such animal diseases.

Under the current regulations, APHIS does not recognize a country as free of certain diseases if that country carries out vaccination for those diseases. However, the OIE International Animal Health Code (Code) recognizes a category of ''free with vaccination.'' To achieve equivalency with the OIE Code, we proposed a ''free with vaccination'' (low risk) classification.

Therefore, we considered it appropriate to propose classifications of regions ''free'' of specific diseases that ranged, in ascending order of risk, from (1) those where the disease is deemed never to have existed or is deemed to have been eradicated, to (2) those that have had a sufficient period of absence of the disease, but present some risk due to trade or adjacency with affected regions, to (3) those that are recently free of a disease, with some risk of residual infection.

We considered the number of risk categories we proposed to be small enough to be manageable, but broad enough to recognize differences in risk discernible on a practical level.

We continue to believe that the number of risk categories we proposed represent a functional approach to characterizing risk. However, after evaluating the practical implications of the proposed regulations based on information submitted by commenters, we have reassessed the benefits of applying the exact same pre-assigned import conditions to all regions grouped in the same risk classification. We have determined that what is gained by making it clear to a region from the outset what it must do to export a particular commodity to the United States is outweighed by a loss of flexibility in customizing import conditions to the particular situation of each region. Further, based on commenter responses to our tentative proposed classification of regions, we believe our characterization of the risk level of a region and the assigned import conditions can be most appropriately determined after the region itself has submitted sufficient data to APHIS to allow us to conduct an assessment of the risk presented by potential imports from the region.

Therefore, in this document we are not making final the system we proposed that would have applied the same import restrictions to each region assigned to one of six risk categories. Instead, as proposed and in accordance with the trade agreements entered into by the United States, we are amending the current regulations to provide for recognition of regions, rather than only countries, for the purpose of importation of animals and animal products. In § 92.1 of this rule, we provide that a region may consist of any of the following:

- A national entity (country);
- Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.);
- Parts of several national entities combined into an area; or
- A group of national entities (countries) combined into a single area.

In a companion document we are publishing in this issue of the **Federal Register** (APHIS Docket No. 94–106–8, ''APHIS Policy Regarding Importation of Animals and Animal Products''), we give notice of the policy we will follow in recognizing regions, assessing the risk presented by potential imports from a region, and determining appropriate import conditions. Our policy will be to determine on a case-by-case basis what import conditions will reduce the risk associated with importations from a particular region to a negligible level. Because levels of risk exist upon a continuum, instead of pre-assigning import conditions based on risk classifications, we will, as a policy, use risk categories as benchmarks to assist regions in evaluating where they can expect to fall on a spectrum of risk levels and what general import conditions may apply.

*Reformatting of Current Regulations*

In this final rule, we are setting forth the procedures for requesting recognition of a region and for requesting that APHIS assess the risk presented by a particular commodity from a recognized region and establish appropriate import conditions. In order to accommodate these procedures in 9 CFR, chapter I, we are moving the provisions of current part 92, ''Importation of Certain Animals, Birds, and Poultry, and Certain Animal, Bird, and Poultry Products; Requirements for Means of Conveyance and Shipping Containers,'' to part 93, and are setting forth the procedures for requesting regionalization and risk assessment in the vacated part 92. The provisions in current part 93 regarding the importation of elephants, hippopotami, rhinoceroses, and tapirs, are redesignated as §§ 93.800 through 93.807.

**Procedures for Requesting Recognition of Regions and Risk Assessment**

As set forth in § 92.2 of this final rule, we will, in general, process applications for regionalization and risk assessment according to the following procedures.

The official of the national government of any country who has the authority in that country to request such a change may submit a request to the Administrator that all or part of the country be recognized as a region, be included within an adjacent previously recognized region, or be made part of a region larger than the country.

Each request for approval to export a particular type of animal or animal product commodity to the United States from a foreign region must be made to the Administrator, and must include, in English, the following information about the region:

1. The authority, organization, and infrastructure of the veterinary services organization in the region.
2. Disease status—i.e., is the restricted disease agent known to exist in the region? If ''yes,'' at what prevalence? If ''no,'' when was the most recent diagnosis?
3. The status of adjacent regions with respect to the agent.
4. The extent of an active disease control program, if any, if the agent is known to exist in the region.

5. The vaccination status of the region. When was the last vaccination? What is the extent of vaccination if it is currently used, and what vaccine is being used?

6. The degree to which the region is separated from regions of higher risk through physical or other barriers.

7. The extent to which movement of animals and animal products is controlled from regions of higher risk, and the level of biosecurity regarding such movements.

8. Livestock demographics and marketing practices in the region.

9. The type and extent of disease surveillance in the region—e.g., is it passive and/or active; what is the quantity and quality of sampling and testing?

10. Diagnostic laboratory capabilities.

11. Policies and infrastructure for animal disease control in the region—i.e., emergency response capacity.

The above information will be made available to the public prior to our initiating any rulemaking action on the request.

Once we have received from a potential exporting region the information necessary to conduct a risk assessment, and have evaluated the risk, we will determine under what conditions an importation can be safely allowed. If we believe the importation can be safely allowed, we will propose in the **Federal Register** to allow such importations, and the conditions under which the importations would be allowed, along with a discussion of the basis for our proposal. We will then provide a period of time during which the public may comment on our proposal. During the comment period, the public will have access, both in hard copy and electronically, to the information upon which we based our risk analysis, as well as to our methodology in conducting the analysis. Once we have reviewed all comments received, we will make a final decision about whether and under what conditions the requested importation may be allowed. If our decision is to allow the importation, we will publish the conditions for importation in a final rule in the **Federal Register**.

Recent rulemakings have provided examples of how the regulations may be amended under the provisions of this final rule. On May 9, 1997, we published in the **Federal Register** a final rule (62 FR 25439–25443, Docket No. 94–106–6) to allow, under certain conditions, the importation of fresh (chilled or frozen) pork from the State of Sonora, Mexico. On June 26, 1997, we published in the **Federal Register** a final rule (62 FR 34385–34394, Docket No. 94–106–5), amended for clarification on August 11, 1997 (62 FR 42899–42900, Docket No. 94–106–7), allowing, under specified conditions, the importation of fresh (chilled or frozen) beef from Argentina, where vaccination for foot-and-mouth disease is still carried out. Although that final rule applied to an entire country, it exemplified the opportunity for a foreign region to request of APHIS an assessment of whether specific import conditions can bring the risk of importation of animals or animal products from that region to a negligible level. As noted above, our policy for assessing risk is outlined in a policy statement we are publishing elsewhere in this issue of the **Federal Register**. Additionally, on June 12, 1997, we published in the **Federal Register** a proposal (62 FR 32051–32053, Docket No. 97–002–1) to regionalize Italy by considering all of Italy except the island of Sardinia free of African swine fever.

As stated above, this final rule allows for the recognition of regions with regard to the importation of animals and animal products. As defined in this final rule, a region need not be an entire, single national entity (country), though it can be. Until we receive requests for regionalization on a case-by-case basis under the provisions of this final rule, we will continue to apply the current regulations to the importation of animals and animal products from foreign countries.

**Scope of This Final Rule**

In response to our proposed rule, several commenters objected to the fact that the proposed provisions applied only to ruminants and swine, and their products. The commenters recommended that the concept of regionalization also be applied to other animals governed by the regulations, including poultry and equine species.

In the Supplementary Information section of our proposed rule, we stated that it was our intent to extend, in the future, the regionalized, risk class approach to the importation of all animals and animal products that are subject to the import regulations in 9 CFR, chapter I. We limited the scope of the proposal to ruminants and swine in the interests of timeliness—i.e., the fact that our proposed approach involved rewriting large parts of 9 CFR part 92 made it advisable to finalize the regionalization changes in several stages. However, the approach we are taking in this final rule involves significantly less rewriting of the current regulations than did the approach set forth in our proposed rule. Because the principles and procedures regarding regionalization and risk assessment that are applicable to the importation of ruminants and swine, and their products, are equally applicable to the importation of other animal species governed by the regulations, we consider it appropriate to extend the principles of regionalization in this final rule to all animals and animal products subject to the import regulations in 9 CFR, chapter I, including poultry, birds, and equines.

**Concerns that Regionalization Will Increase the Risk of Disease Introduction**

Some commenters expressed general concern that the provisions we proposed for regionalization and levels of risk would increase the risk of animal diseases being introduced into the United States. Other commenters expressed particular concern about the possibility of the introduction into the United States of emerging diseases, such as bovine spongiform encephalopathy (BSE). We are acutely aware of the concern of the U.S. public that livestock in this country continue to be protected from disease introduction. As noted above, until APHIS receives a request for regionalization, the imports into the United States will continue to be governed by the current regulations. When requests for regionalization are received, APHIS will evaluate them on a case-by-case basis, and determine what, if any, import conditions can bring the disease risk presented by the imports to a negligible level. Throughout the process of analyzing any request for regionalization, APHIS will provide the public the opportunity to evaluate the information the region has submitted to APHIS in requesting regionalization. The public will then be given a formal opportunity to comment on the proposed action. No request for regionalization will be made final until APHIS has taken into consideration all comments submitted by the public during the comment period.

Several commenters stated that attention needs to be paid to identifying diseases that do not exist in the United States, but that may put the livestock population at risk. The commenters stated that as major diseases such as foot-and-mouth disease (FMD) or classical swine fever (hog cholera) are confined to limited areas of countries, or are eradicated, it will no longer be possible to rely on import restrictions due to the presence of these diseases to guard against the importation of other diseases of concern. Consequently, said the commenters, it will become increasingly important for APHIS to have the appropriate resources,

diagnostic capabilities, and expertise to determine what other diseases are potential risks. The commenters cited examples of diseases of potential concern. We agree with the commenters and concur that changing disease and trade conditions require a broad view regarding what diseases require regulation. We address this broadened concern in our notice of policy regarding regionalization and risk assessment, set forth elsewhere in this issue of the **Federal Register**.

Several commenters stated that the list of diseases of concern should include all disease subject to a control or eradication program in the United States. We share the commenters' view that import restrictions should be in place to guard against the movement into this country of diseases that currently exist in the United States but that are subject to a domestic control or eradication program. These diseases of concern are addressed by the current regulations and by the policy statement we are publishing elsewhere in this issue of the **Federal Register**.

Some commenters stated that a comprehensive emergency plan should be in place prior to implementation of the revised regulations. Currently, the Secretary of Agriculture has the authority to implement necessary measures to control and eradicate animal disease in this country. APHIS has had in place for a number of years resources and procedures for responding to disease outbreaks on an emergency basis.

One commenter recommended that the regulations specifically state that APHIS has the option to restrict imports because of new or emerging diseases. We do not consider it necessary to include such a statement in the regulations. For years, APHIS has enforced import restrictions on new or emerging diseases, and we will continue to do so.

Some commenters stated that the regulations should contain provisions for relaxing emergency measures when they are no longer warranted. Just as it does under the current regulations when a disease risk has been eliminated, APHIS will take action through rulemaking, subject to public comment, to relieve restrictions that no longer appear warranted.

A number of commenters expressed concern that implementation of the proposed regulations would represent a huge and costly workload for APHIS, and that administrative problems in implementing the proposal would create barriers to trade. The commenters stated that APHIS lacks the budget and infrastructure to administer the proposal in a timely manner consistent with sound animal health intervention and exclusion strategies. Other commenters stated that the provisions of the proposed rule were ill-equipped to deal with developing situations, that it will be difficult for APHIS to maintain current information on countries' importing practices, and that the information regarding risk classification will always be months or years out of date. As an alternative to the ''notice-and-comment'' procedures currently followed by APHIS under the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*), some commenters suggested that all regional disease classifications and decisions be made available electronically, with the CFR merely establishing authority to classify and methods to classify and make changes. According to the commenters, requests for a change in status could be updated by a press release available electronically and comments could be solicited in like manner. Several commenters recommended that the regulations allow the United States to accept on a provisional basis new risk classifications established by other countries, pending U.S. verification.

We believe that a number of the concerns raised by the commenters are addressed by the changes we are making to the proposal in this final rule. As noted above, we will continue to apply the current regulations until we receive requests for regionalization. We are not making final our proposed system of assigning each foreign region to one of six risk classifications. Under this final rule, we will not attempt to assess the risk of importations from a region until the region itself has provided all of the information necessary for conducting such an assessment, although we will take into account any information available to us from other sources.

Because this final rule provides options not available under the current regulations, APHIS recognizes that, especially initially, it will face an increased workload when this rule is made effective. A major impetus to the publication of this final regulation is the U.S. commitment under the North American Free Trade Agreement and the WTO–SPS Agreement. As a signatory of these agreements, the United States has agreed to accept the principle of regionalization and to allow the importation of animals and animal products from regions of low disease prevalence, subject to whatever mitigating measures are necessary to safeguard livestock in the United States.

We are committed to implementing, where appropriate, regionalization in individual cases as quickly as possible once we have received and reviewed sufficient valid data from and about the requesting region, and have conducted a risk assessment of the importation requested. However, because of the potentially broad interest regarding importations of animals and animal products, we consider it necessary to ensure that all members of the public are made aware of potential changes through rulemaking.

Under the APA, APHIS must, in most cases, provide public notice of proposed changes to the regulations through publication of a proposed rule in the **Federal Register**, and provide interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments. Within these requirements, APHIS is examining ways to streamline the review process, including the development of a data-handling mechanism to receive and store information related to animal health and veterinary infrastructure. Additionally, APHIS plans to increase its resources in the area of risk assessment. With regard to electronic notification of proposed rulemaking, APHIS currently notifies the public electronically of various actions taken by the Agency. However, Administrative Procedure Act requirements for notice and comment rulemaking are not fulfilled until the action is published in the **Federal Register**.

**Recognition of Equivalency and Foreign Regionalization**

One commenter recommended that the regulations allow the Administrator of APHIS to enter into an agreement with a foreign country to recognize the equivalency of that country's rules. We consider the concept of equivalency to be provided for in this rule. It allows the United States, based on information made available to it by its trading partners and other sources, to identify, along with those trading partners, specified risks from a region on a disease-by-disease and commodity-by-commodity basis, and identify mutually agreeable risk management measures to reduce risk to a negligible level. Equivalency exists when countries agree that each others' risk management measures are appropriate and when they identify commodities for which import measures that may not be identical for the same commodity are needed to address the differences in prevalence of restricted agents, geographic or demographic factors, or animal health infrastructure.

It is the responsibility of the exporting region to demonstrate to the importing country that the region meets standards

equivalent to the importing country's standards or other acceptable standards. Certainly, in those cases where the United States and some other country have historically developed animal health standards for common diseases, there is no reason to expect that such interaction will not continue.

Among the comments received was the recommendation that the United States should recognize regions that are created and maintained up-to-date by other bodies, such as the European Community (EC). The comment stated that the EC has been divided into many regions for various diseases and, because the areas are constantly achieving results in disease eradication, the areas recognized by the EC as free are constantly expanding. Because of this, the commenters expressed concern that U.S. regulations would quickly become out of date. The commenters recommended that a region be defined as the area recognized by the EC as being free from a particular disease in accordance with accepted criteria, pending U.S. examination of the matter.

As discussed above, our overriding goals in implementing regionalization are to facilitate trade in accordance with international agreements while maintaining the level of biosecurity afforded by the current regulations. We believe the provisions of this final rule, and our policy toward regionalization and risk assessment published in this issue of the **Federal Register**, meet these dual goals. As discussed above, however, APHIS rulemaking must be carried out in accordance with the APA, with an opportunity provided for public comment on changes to the regulations. At present, APHIS is developing a proposal to recognize regions established by the EC with regard to disease status, based on information submitted in a request by the EC.

Some commenters recommended that, to make the regulations more transparent, procedures should be set forth for situations where there are no specific requirements stated. As noted above, the companion policy statement we are publishing in this issue of the **Federal Register** outlines the procedures we intend to take in evaluating requests for regionalization and importation of animals and animal products. As we discussed, we will conduct such evaluations in a transparent manner open to public review and comment.

Several commenters recommended that APHIS review what the commenters referred to as internationally accepted guidelines for regionalization, risk analysis, and risk assessment. The commenters specifically referred to the following documents: (1) Cane, B.G., ''The Concept of Regionalization in Establishing Disease-Free Areas,'' OIE comprehensive reports on technical items presented to the international committee or to regional commissions, 1994; (2) Kellar, J.A., ''The Application of Risk Analysis to International Trade in Animals and Animal Products,'' OIE comprehensive reports on technical items presented to the international committee or to regional commissions, 1992; (3) Morley, R.S., Acree, J., Williams, S., ''Animal Import Risk Analysis (AIRA): Harmonizing our Approach,'' OIE comprehensive reports on technical items presented to the international committee or to regional commissions, 1990–1991; and (4) ''OIE International Health Code,'' Section 1.4, chapters 1.4.1–1.4.5, 1994 updates. In the process of developing the proposed rule, APHIS reviewed all of the sources cited. Wherever possible, concepts from these references were incorporated into the proposal. We have also incorporated concepts from these references into the policy on regionalization and risk assessment we are giving notice of in this issue of the **Federal Register**.

**Comments on Information Considered in Assessing Risk**

Among the requirements set forth in the proposal for applying for recognition of risk classification for a region was the requirement that the Chief Veterinary Officer of the region submit to APHIS a completed questionnaire relating to the specific disease in question. Several commenters requested that this questionnaire be published in the regulations. Several commenters asked for clarification of how the United States would expect regions to demonstrate freedom from restricted disease agents. One commenter requested that APHIS publish the procedures it will use to communicate with nations so that countries will have the opportunity to document their animal disease situation in order to gain the appropriate classification. As stated above, we are not making final our proposed system of risk classification, but we are setting forth in § 92.1 of the regulations procedures for applying for regionalization, for assessment of the risk presented by imports from a region, and for determination of appropriate import conditions.

Some commenters stated that the proposed rule placed undue emphasis on the influence that neighboring regions have on each other's disease status. According to the commenters, although border controls are often necessary, they are not as important in cases where the epidemiology of disease agents, combined with differing husbandry factors, effectively prevents establishment of a disease in a neighboring region. Although we consider proximity between regions generally of importance with regard to contagious diseases, we agree that in some cases the proximity of one region to another is irrelevant because of varying climatic or other ecological factors. This is true in the United States with a disease such as bluetongue, which has never become established in the northeastern part of the country due to ecological factors, despite a lack of interstate movement controls. Given equivalent factors, however, vector-borne diseases might readily move across regional boundaries in spite of border controls. For this reason, proximity to affected regions must be considered a factor in determining disease risk, and is included in the information we are requesting under this rule in applications for regionalization. Under the approach we have adopted in this final rule and our policy toward regionalization, proximity will be considered as a factor in assessing the risk of disease introduction, but will not be given a predetermined weight in the assessment process.

In related comments, some commenters stated that, because many diseases listed on the OIE ''List B'' can easily be contained within a herd or flock, the status of a contiguous region is not relevant for many List B diseases in determining the risk class of the region under consideration, particularly when effective border control barriers are in place. As we stated above with regard to the issue of proximity, the status of a contiguous region will be considered as a factor in assessing the risk of disease introduction, but will not be given a predetermined weight in the assessment process. As implied by the commenters, the concern about contiguous regions is not necessarily about the ability of the disease agent itself to be transmitted across the border, but more so about the possibility of undeclared illegal movements of infected animals or products, or the straying of loose animals or carrier wildlife across the border. While effective border controls are a crucial consideration in assessing the risk posed by importations from a region, we do not consider them alone to be a guarantee that the movement of disease from a contiguous region will be eliminated.

One commenter expressed concern about what the commenter considered a lack of specific criteria for how we

would evaluate the veterinary infrastructure in the exporting region. We believe this issue relates to the information, discussed above, that will be required regarding the authority, organization, and infrastructure of the veterinary services in a region. We consider the evaluation of infrastructure in any region to necessarily be somewhat subjective. Until the OIE or some other organization develops an objective measure of infrastructure, we believe the best way to evaluate infrastructure is on a case-by-case basis, by means that, in some cases, will include on-site visits.

**Concerns Regarding the Effect of Regionalization on Wildlife**

One commenter expressed concern about the potential effect of the proposed risk classification system on wildlife. The commenter was concerned that some countries might contain or eliminate wild animals in order to ensure that there are no pockets of disease that might prevent the countries from attaining a particular risk classification. We consider the commenter's concerns to be addressed in large measure by our decision not to make final the system of establishing a risk classification system based on pre-defined criteria. However, each country must make its own decisions concerning such matters. APHIS will prepare an environmental assessment specific to the region in question prior to promulgating a final rule to create a region.

**Comments Addressing Specific Conditions for the Importation of Animals**

Some commenters stated that, under the proposed regulations, cases would arise where animals would be required to undergo quarantine simply to eliminate the presence of a bacterial disease. According to the commenters, in these cases, the full quarantine regimen should not be necessary, and the regulations should allow for equivalent alternative mitigating measures. The commenters suggested as possibilities the conduct of additional tests in the country of origin, followed by isolation and testing in the United States. It is not clear to us from the comments whether the commenters are recommending elimination of certain of the quarantine requirements in place under the current regulations. Historically, we have found the post-importation period of quarantine in the United States necessary as a period for observing the imported animals for disease, and we do not consider it advisable to eliminate these requirements at this time.

Several commenters stated that the proposed 15-day importation quarantine period was insufficient to allow for incubation of diseases of concern. It is not clear to us from the comments exactly which proposed importation requirements the commenters are referring to in each case. Under the current regulations, except for cattle from Central America and the West Indies, which may be quarantined for 7 days under certain conditions, and except for cattle and certain other ruminants from Canada and Mexico, all ruminants imported into the United States must be quarantined for not less than 30 days from the date of arrival at the port of entry. Under the current regulations, swine must be quarantined for not less than 15 days from the date of arrival at the port of entry. Based on our experience enforcing the regulations, we consider these quarantine requirements adequate and are retaining them in this final rule.

Several commenters expressed concern that transhipments of animals and animal products through high risk areas could cause contamination of the products or animals. Some commenters stated that developing countries have insufficient resources to monitor many of the most serious foreign animal diseases of concern. The commenters expressed concern that, in many countries, the illegal movement of livestock from higher-risk to lower-risk regions would be hard to detect, control, and prevent. Each of these concerns focuses on two of the key factors on which we will request information under the procedures for applying for regionalization—border controls and the infrastructure necessary to monitor and enforce the movement of animals and products from, into, or through the region. We will be obliged to characterize a requesting region a high risk or an unknown risk if the country in question lacks the infrastructure, or does not have access to the resources necessary, to enforce sanitary provisions that would support regionalization or to monitor for animal diseases of concern to the United States.

A number of commenters expressed concern that imported animals may serve as a source for emerging diseases or those of long incubation. To facilitate tracking of animals, commenters recommended that a permanent identification be placed on imported animals. We do not consider the risk of disease introduction to be any greater under this final rule than under the existing regulations. Under the current regulations, in most cases we do not require either permanent identification of imported animals or a permanent record of their final destination. The feasibility of heightening identification and tracking of imported animals is under review by APHIS. In the meantime, we support the efforts of the livestock industry to develop a system of identification that meets its needs.

Commenters argued both for and against including destination factors in determining import conditions. Some commenters stated that considering destination risk is required by the WTO–SPS agreement, and that failure to consider destination risk makes it illogical for the United States to impose post-importation conditions on animals and animal products if those conditions do not also apply to native U.S. animals. Commenters cited the need to assess the risk of animal importations in which vector-borne disease agents represent hazards, and, in particular, the duration of viraemia and competence of vectors. The commenters also stated that factors to be considered should include the exposure of domestic animals to infected products, modes of transmission, and the amount of infectious agent present that is sufficient to cause infection. Conversely, some commenters supported the premise that any importation of a restricted agent is undesirable. The general policy we have followed under the current regulations is to require import conditions to reduce any risk of introduction of a disease of concern at importation to a negligible level. We are retaining this policy under this final rule.

Some commenters recommended that diagnostic tests approved by the OIE automatically be approved, under the regulations, for use on animals being imported. The commenters also stated that, to ensure openness and consistency, any other tests that would be accepted be published in the rule. Tests approved by the OIE would generally meet the scientific validity requirements for an equivalent approved test. However, we consider it necessary for the APHIS Administrator to have the flexibility to not use any test if evidence shows that it is not valid, even though it might currently be included in the OIE list of approved tests. Also, the Administrator must have the flexibility to use new tests when deemed appropriate, even if they have not been added to the approved list for OIE. Therefore, we have decided not to publish in the regulations a list of tests approved for use on animals imported or to be imported into the United States.

Several commenters recommended that the maximum time allowed for imported animals to be moved to

slaughter be reduced from 2 weeks to as little as 48 hours. The policy of allowing up to 2 weeks for movement to slaughter is not new to the proposed rule. It exists in and has been followed under the existing regulations. Although we are making no changes based on these comments at this time, we will further examine the commenters' recommendation and take whatever action we deem appropriate.

Several commenters questioned the need for import permits as a requirement for importation. The commenters stated that such permits serve no purpose. Some commenters stated that if import permits can be withdrawn without notice or explanation, such practice would be contrary to SPS Article 7. As we explained in the Supplementary Information section of our proposed rule, the primary purpose of import permits is to assure that there is space at a quarantine center for imported animals that must be transported by air or sea to the United States. Such import permits are necessary to avoid problems, both economically and with regard to the humane treatment of animals, in refusing entry to a shipload of animals that have arrived at a port without prior notice and without a reservation for space.

One commenter asked for clarification of the term ''restricted use and movement,'' as used in the Supplementary Information section of the proposed rule when discussing risk mitigation measures. In general, restricted use and movement is used primarily to reduce potential losses should a disease agent be introduced. By restricting the distribution of potentially infected animals, the number and distribution of native animals that could be exposed is limited. An example of how we have used, and continue to use, this mitigation measure is in the importation of amimals from a country where a particular disease exists, solely for residence at approved zoos where their movement is restricted.

One commenter stated that opportunities for electronic certification should be considered. We are not certain what the commenter meant by ''electronic certification.'' We assume the commenter was referring to electronic transmission of health certificates. Although to date we have not received a request to accept electronic health certification for imports into the United States, we are receptive to suggestions we might receive from the public regarding the use of such certification.

One commenter stated that the capacity and costs of quarantine centers, particularly the Harry S Truman Animal Import Center (HSTAIC), should not become a trade barrier. Importation though HSTAIC is a method of allowing the importation of animals from certain high-risk situations that would otherwise require total prohibition of the importation. APHIS recommends that importers consider importing breeding material through embryos or semen whenever possible, to avoid the extra costs and potential delays that use of HSTAIC entails.

Some commenters stated that, depending on the commodity under consideration, only the viremic state of a disease might be of concern, with the incubatory and convalescent states representing negligible risk. We agree that the situation described by the commenters is true for some diseases, depending on the mode(s) of transmission. However, we do not agree that an animal in the incubatory stage represents a negligible risk. Because diagnosis at the incubatory stage is often difficult, making a distinction among the stages when determining disease risk will have little practical effect on establishing import conditions.

In our proposed regulations we used the term herd. In the ''Definitions'' section to the regulations regarding ruminants and swine, we included no period of time that animals would need to remain together to be considered a herd. Some commenters stated that the definition of ''herd'' should indicate that, to constitute a herd, the animals must have been together for a specified minimum period of time. We do not consider it advisable to make such a change. In certain situations, how long the animals have been together is less important than the origin of the animals in the group. For instance, if all animals in the group have been assembled from herds certified free of a disease under a disease eradication program, the length of time the animals have been together is not significant.

Some commenters addressed the requirement in proposed §§ 93.415(d)(3) and (4) that ruminants from regions proposed to be classified as Risk Class R3 or R4 for FMD undergo pre-embarkation quarantine under APHIS supervision in a facility approved by the Administrator. The commenters stated that this requirement shows an unwarranted disregard for the scientific, ethical, and certifying ability of the veterinary authorities in exporting countries. Although this final rule does not categorize regions as Risk Class R3 or R4, and does not require APHIS supervision of pre-embarkation quarantine, it retains the requirement of the current regulations that ruminants and swine imported from countries not considered free of FMD be quarantined in a pre-embarkation quarantine facility approved by the Administrator. Although we agree that, in many cases, reliance on the veterinary authorities in an exporting country would provide adequate approval and inspection of a facility, we consider it necessary for the Administrator to have authority to ensure that in all cases the facilities in question meet adequate standards.

Several commenters stated that APHIS should consider implementing recommendations from the ''Border States Consensus Document.'' The document referred to represents a consensus by U.S. States that share a border with Mexico regarding recognition of efforts within Mexico to eradicate *Mycobacterium bovis* (tuberculosis). The recommendations of the consensus document, including recognition of certain States in Mexico as being free of tuberculosis, can be accommodated by the procedures for requesting recognition of regions set forth in this rule.

A number of commenters addressed the issue of how camelids should be addressed in the regulations. Some commenters recommended that they be removed from the definition of ''ruminants.'' The commenters stated that camelids are not true ruminants, that marked anatomic and physiologic differences between camelids and ruminants exist in many organ systems, and that llamas and alpacas appear to be resistant to and unlikely to spread several important livestock diseases, including FMD, *M. bovis*, and *Brucella abortus*. Other commenters expressed concern regarding the potential disease risk posed by camelids.

''Webster's New International Dictionary'' defines *Ruminantia* as follows: ''A division of even-toed hoofed animals including those that chew the cud, as the oxen, sheep, goats, antelopes, deer, chevrotains, and camels. They are divided into three groups; the *Pectora* or true ruminants * * * the *Tylopada*, or camels and llama * * * and the *Chevrotains*.'' We have many of the same disease concerns with camelids as with other ruminants. However, we agree with the commenters that there may be some practical disease risk differences between camelids and cattle. Although we are making no changes to this final rule in response to these comments, we are reviewing this issue and are considering addressing it in future rulemaking.

**Comments Addressing Regulations Governing the Importation of Meat and Meat Products**

A small number of commenters expressed concern that the import conditions for meat products from certain of the proposed risk class regions required that the backbone be removed from the carcass of the animal, even though the meat grading standards of the Department's Agricultural Marketing Service (AMS) require foreign beef to have a country-of-origin mark on the carcass 4 inches from the backbone. Because we are not making final the import conditions based on risk classifications, in a number of cases the provisions the commenters are referring to are not set forth as general requirements. However, we consider the requirement that a carcass be deboned an important one in reducing the risk of FMD-transmission from meat, and expect to apply it to future importations as appropriate. For example, in our June 26, 1997, final rule regarding the importation of fresh, chilled or frozen, beef from Argentina, one of the requirements for importation of the meat was that it be deboned. The AMS standards in 7 CFR 54.4 *et seq.* state that grading is done only on carcasses and is voluntary. We consider concerns regarding disease risk to take precedence over grading standards for meat, which could be done on the carcass before the meat is deboned.

One commenter stated that, in § 94.15 of the proposal, regarding cancellation of compliance agreements, the regulations indicated that certain actions by APHIS will be taken ''as promptly as circumstances allow.'' The commenter requested that the time allowed for action by APHIS be specified. The provisions referred to by the commenter are set forth in the current regulations. Based on our experience enforcing the regulations, we consider the actions taken by APHIS to have been taken in a timely manner and do not consider it necessary to revise the provisions in question at this time.

In §§ 94.1 (e) and (g) of the proposed regulations, we set forth proposed requirements for the importation of fresh (chilled or frozen) meat from ruminants and swine from regions classified as Risk Class R2 or R3 for FMD. Among the proposed import conditions was the requirement that the meat reach a pH of 6.0 or less in the loin muscle. In the Supplementary Information section of our proposed rule, we stated that acidic or alkaline conditions readily kill the FMD virus. One commenter took issue with this statement, stating that research has shown that although a pH below 6.0 or above 11.5 will inactivate the FMD virus, the virus resident in the micro-environment of animal tissue—such as lymphatic tissue, bone marrow, or coagulated blood—is resistant to inactivation over a practical pH range.

The proposed requirements referenced by the commenter are not included in this final rule because they were import conditions particular to two risk categories that we are not including in this rule. However, maturation of meat to an appropriate pH level is a proven method of killing the FMD virus, and is one of the conditions we set forth in our June 26, 1997, final rule for the importation of fresh (chilled or frozen) meat from Argentina. In the Supplementary Information section of that final rule, we stated that although we agreed with the commenter, the regulations as proposed already addressed the concerns raised. We stated that we assumed that by ''micro-environment'' the commenter was referring to those areas of the meat in the carcass that are in the immediate area of the bones, lymphatic tissue, or coagulated blood, and noted that one of the proposed conditions for importing fresh (chilled or frozen) meat from Argentina was that all bone, blood clots, and lymphoid tissue be removed from the meat. However, in that final rule, based on the comment and the literature available to us, we amended the regulations as proposed to require that a pH level of 5.8 or less be reached before the meat may be imported.

The proposed importation requirements for cured or cooked meat from regions classified as Risk Class R3, R4, or RU for certain diseases included the requirement that the meat be deboned. This requirement for deboning is also included in the current regulations. Some commenters, addressing the proposal, stated that deboning should not be required for cured or cooked meat because such treatment already reduces the disease risk from the meat to an acceptable level. We do not agree with the commenters that removal of bones is not necessary in meat that is otherwise cured or cooked in accordance with the regulations. The presence of the bone in the meat makes it difficult to determine whether the bone has been treated throughout to the extent necessary to destroy the restricted disease agent. For example, in the case of FMD, unless some way is developed to determine the temperature level within the bone, there is no way of determining whether the entire piece of meat, including the bone, has been heated to the temperature necessary to kill the FMD virus.

**Comments Regarding Bovine Spongiform Encephalopathy**

Some commenters took issue with our statement in the Supplementary Information section of our proposal that bovine spongiform encephalopathy (BSE) ''is thought to have been introduced into cattle from scrapie-infected sheep brains that were included in rendered protein meal added to cattle feed.'' The commenters stated that the original source of BSE is unknown, and that it would be more accurate to say that the BSE epidemic seems to be the result of a single source infection resulting from BSE-infected meat and bone meal. The statement we included in our proposed rule was based on the information available to us at the time the proposal was developed. At this time, we agree with the commenters as to the limits of what can be concluded regarding the origins of BSE.

One commenter questioned the rationale for allowing the importation of embryos from BSE-affected regions, while, according to the commenter, the OIE takes a cautious approach. The commenter apparently misread the proposed regulations. Embryos from countries affected with BSE are currently not permitted importation into the United States, and the proposed regulations did not include provisions allowing the importation of such embryos.

Several commenters stated that because transmissible encephalopathy occurs in cervidae in the United States, a ban on the feeding of ruminant protein should be in force in the United States. Other commenters stated that such a ban would eliminate the possibility that an infected animal, even if imported, could transmit the disease to another. Although APHIS does not have the authority to ban the feeding of ruminant protein, it should be noted that in a final rule published on June 5, 1997 (62 FR 30936–30978, Docket No. 96N–0135), the United States Department of Health and Human Service, Food and Drug Administration, established regulations controlling the use of animal protein derived from mammalian tissue in ruminant feed.

**Proposed Provisions Not Being Made Final**

A large number of the issues raised by commenters regarding our proposed rule addressed provisions of the proposed rule that are not included in either the current regulations or in this final rule. Therefore, pending future requests for regionalization, many of the concerns raised regarding the proposed

rule are no longer relevant. These include concerns raised by commenters regarding the following: Differences between the current regulations and the proposed rule regarding import requirements for animals and animal products, including the concern that the proposed regulations would, in some cases, be more restrictive than the current regulations; the relationship between the ''qualitative'' and ''quantitative'' options for assessing risk under the proposed rule; criteria for assigning regions to particular risk classifications; whether the quantitative risk assessment option could be scientifically supported; differences between the proposed import requirements and the standards of the OIE Code; differences between the proposed import requirements and requirements governing U.S. interstate movement; classification as ''restricted disease agents'' of agents not included on the OIE ''A'' or ''B'' list of diseases; concerns that the proposed import requirements would not allow consideration of ''equivalency'' with an importing region's mitigation measures; that criteria for border controls of regions were too rigid; importation requirements relating to specific disease agents, including ectoparasites; whether the proposed import requirements would preempt State requirements; that certain terms used in the proposed rule were unclear and required definitions; that the proposed restricted disease agents did not seem to be treated differently based on potential impact; and the risk classification of certain countries.

Similarly, commenters made several requests that are no longer relevant. These include: That the regulations clarify which animals would be considered in determining the risk classification of a region; that embryos from ''high-risk'' areas be considered ''low-risk'' if treated in accordance with internationally recognized treatment standards; that the practice of vaccination not necessarily affect a region's risk classification; that the United States evaluate its own status and programs with regard to the requirements of the proposal; and that APHIS publish risk analysis documentation to support the prohibition of meat, embryos, and semen from certain risk class categories.

*Other Proposed Changes to the Regulations Being Made Final*

We proposed to make a number of changes to the regulations that were not directly related to the concepts of regionalization or risk assessment. In all cases but one, we received no comments regarding these proposed changes. We discuss below the amendments we proposed, any comments we received, and actions we are taking on the proposed changes in this final rule.

We proposed to consider the entire country of Canada as presenting a slight risk for the introduction of *Brucella abortus* and as a negligible risk for *B. melitensis.* Under the proposed import conditions for such a risk classification, no testing for these diseases would be required for cattle from Canada from provinces free of brucellosis. We continue to consider it warranted to allow cattle from Canada from brucellosis certified-free provinces or herds to enter the United States without brucellosis testing, and are amending § 92.418 of the current regulations to provide that such testing is not necessary.

We are adding to § 94.0, ''Definitions,'' the definitions we proposed for *Cervid, Contact, Pink juice test, Region, Ruminants,* and *Veterinarian in charge.*

Current § 94.7 includes provisions for the disposal of animals, meats, and other articles ineligible for importation under the regulations regarding rinderpest and FMD in current § 94.1. We proposed to expand the disposal regulations so that they refer to African swine fever, hog cholera, swine vesicular disease, and BSE, as well as to rinderpest and FMD. In this rule, we are making final those expanded provisions.

We are making final at § 94.12(b)(1)(iii)(B) of the regulations the provision we proposed that pork or pork products consigned from the port of arrival to an approved establishment must be moved under Customs or USDA seal, and must be otherwise handled as the Administrator may direct in order to guard against the introduction and dissemination of swine vesicular disease. The required seals may not be broken except by persons authorized by the Administrator to do so.

We proposed under § 94.9 to allow the limited transiting of meat and other animal products not otherwise eligible for entry into the United States, to allow for offloading from one means of conveyance at the port of arrival onto a second means of conveyance scheduled for immediate departure from the United States. One of the conditions for such limited movement was that the meat or other animal product not be stored for more than 24 hours at the maritime or airport port of arrival. Commenters requested that the allowable time for holding or storage be extended to 48 hours, to allow for cargo movement logistical problems. We agree with the commenters that a longer period of time at the port is sometimes necessary to make connections between ships. As long as the meat and other animal products are securely contained aboard the carrier or while being offloaded, and as long as their overland movement in the United States is confined to that port of arrival, we believe it is warranted to allow the meat or other animal products to be held at the port up to 72 hours. We are adding provisions for such limited transit at § 94.15(d) of this final rule.

We are making final the change we proposed to § 94.16(b)(2) of the current regulations to remove the requirement that certain dry milk and dry milk products intended for importation be processed for human food. The provisions that require that dry milk or dry milk products intended for importation from countries in which rinderpest or FMD exists be processed for human food also require that the dry milk or dry milk products be processed in a manner approved by the Administrator as adequate to prevent the introduction or dissemination of livestock diseases into the United States. Dry milk or dry milk products that are processed in a manner adequate to prevent disease can be safely processed for uses other than human food.

We are making final at § 96.10 our proposed removal of references to specific cities in which casings that arrive in the United States without certification may be disinfected, and are providing that such casings may be forwarded to a USDA-approved facility for disinfection. We are making this change because the facilities in the cities specified are no longer in operation. Currently, all casings entering the United States under 9 CFR part 96 are entering in accordance with § 96.4, which allows the casings to be entered if the casings are accompanied by certification that they were derived from healthy animals that were inspected ante- and post-mortem. In the event of an intended importation of casings that would need to be disinfected in the United States, such disinfection could be done at any facility approved by APHIS.

As proposed, we are removing current §§ 96.15 and 96.16, because they specify administrative procedures that have been discontinued for a number of years.

**Clarification of Final Rule Regarding the Importation of Pork from Sonora**

As noted above, on May 9, 1997, we published in the **Federal Register** a final rule to allow the importation of fresh (chilled or frozen) pork from the State

of Sonora, Mexico. The provisions allowing this importation were added at a new § 94.20. At § 94.20(a), we specified that the pork must be meat from swine that have been raised and slaughtered in Sonora. It was also our intent that the swine from which the meat comes have been born in Sonora. In this final rule, we are amending § 94.20(a) to clarify this intent.

**Clarification of Terminology**

In current part 94, we refer in a number of cases to meat that is ''fresh, chilled, or frozen.'' The intent of this phrase is to refer to fresh meat that is either chilled or frozen. We are making nonsubstantive punctuation changes in part 94 to clarify this intent by using the wording: ''fresh (chilled or frozen).''

**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.

**Executive Order 12866 and Regulatory Flexibility Act**

This rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

In this rule, we are establishing procedures for recognizing regions, rather than only countries, for the purpose of the importation of animals and animal products into the United States. We are also establishing procedures by which regions may request permission to export animals and animal products to the United States under specified conditions, based on the regions' disease status. These changes to the regulations are in accordance with international trade agreements entered into by the United States. We are also allowing, under certain conditions, the unloading and reloading at the port of arrival of meat and other animal products otherwise prohibited entry into the United States. Additionally, we are removing the requirement that cattle from brucellosis certified-free herds, provinces, and territories in Canada be tested for brucellosis before being imported into the United States, and are making several minor changes in our requirements for importing animals and animal products that will relieve or clarify some import restrictions while continuing to protect U.S. livestock and poultry from foreign animal diseases.

**Regionalization**

The fundamental purpose of the changes we are making to the regulations with respect to regionalization—primarily changing the word ''country'' to ''region'' and setting out the procedures that a region must follow to be recognized as a region—is to establish a framework for a regional approach to the importation of animals and animal products and, thereby, fulfill U.S. commitments under international trade agreements. In developing this rule and the policy statement published elsewhere in this same issue of the **Federal Register**, we have explicitly recognized that there are identifiable and measurable gradations of risk presented by animals and animal products and that these gradations are often tied more to factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of disease control programs than to national political boundaries. Accordingly, we have adopted an approach that assesses risk along a continuum and responds to the risks presented from an importation on a case-by-case basis.

Because this framework will not be fully implemented until we receive a new request to allow the importation of animals or animal products into the United States, and because we do not know the number or sources of requests we will receive in the future, we cannot estimate the economic impact of this rule as stipulated in E.O. 12866. We are therefore committed to performing a risk assessment and cost-benefit analysis on a case-by-case basis for each request we receive in the near future.

**Removal of Requirement for Brucellosis Testing of Cattle From Canada**

We are making final a provision to allow cattle from certified brucellosis-free herds, provinces, or territories in Canada to enter the United States without brucellosis testing.

All domestic herds in Canada are free of brucellosis, and therefore no brucellosis testing would be required for any cattle imported to the United States. Expected cost savings can be estimated using the number of breeding cattle imported from Canada in Fiscal Year 1996: 29,340 head. Assuming a laboratory cost of $3 to $4 per test (based on USDA National Veterinary Services Laboratories user fees), Canadian operations exporting breeding cattle to the United States may save a total of between $88,020 and $117,360. (Other costs associated with assembling of the cattle at the time of testing will remain, since physical inspections will still take place.)

The cost savings are very small compared to the average value of the cattle. In 1996, the average price per animal of cattle imported from Canada that weighed 200–320 kg was $332. (Based on the way the price data is made available, this price includes the value of both slaughter and non-slaughter animals. Under the current regulations, cattle intended for immediate slaughter are not required to be tested.). The average price of nonslaughter cattle (not including purebreds) weighing more than 320 kg was $1,152. Thus, the savings represent no more than 1 cent of every dollar of the smaller animals' average cost, and about 3 cents of every 10 dollars of the larger animals' average cost. The average price of purebred cattle imported from Canada in 1996 was $810, of which the cost savings represents less than 5 cents of every 10 dollars. The fraction of this savings, if any, that may be realized by U.S. livestock buyers, would be smaller still. The economic impact for U.S. entities will be negligible.

**Transiting of Certain Animal Products**

This rule allows the unloading and reloading at the port of arrival of meat and other animal products otherwise prohibited entry into the United States. Under certain conditions, such products may be unloaded from a means of conveyance and be held at a port for up to 72 hours before reshipment from the same port by a second means of conveyance.

U.S. imports would not be affected by this rule change. Consequently, the only U.S. entities for which there could be impacts would be ones taking part in the marine or air transshipments, by providing shipping or temporary storage of the transshipped products.

As an example, under this rule, meat from Europe prohibited by the United States but eligible for entry to particular Caribbean or South American countries, could be transshipped at U.S. ports. This could result in cost savings for shipping companies, depending on shipping logistics, as well as additional business for the ports providing transshipment services.

According to available information, in 1994 there were 129 U.S. firms in the SIC category ''Deep Sea Foreign Transportation of Freight.'' Nearly 90 percent (115 firms) were small entities by the Small Business Administration's definition of fewer than 500 employees. There were also 577 U.S. firms in 1994 in the category, ''Marine Cargo Handling.'' For this industry, designation as a small entity is

determined by annual receipts of less than $18.5 million. An estimated 80 to 90 percent of U.S. firms handling marine cargo are small entities.

With respect to firms that could be involved in air transshipments, in 1994 there were 520 U.S. firms classified under ''Scheduled Air Transportation'' and 1,475 U.S. firms classified under ''Nonscheduled Air Transportation''. Of these firms, 86 percent and 95 percent, respectively, had less than 500 employees. For both SIC categories, the Small Business Administration's definition of a small entity is one with fewer than 1,500 employees. There were also 2,864 U.S. firms in 1994 comprising the category, ''Airports, Flying Fields, and Airport Terminal Services.'' An estimated 85 percent of these firms are small entities, as determined by annual receipts of less than $5 million.

If U.S. shipping and cargo handling firms were to be affected by this regulation, it is likely that at least some of them would be small entities. However, because the transshipment that would be allowed by this rule change currently does not take place, there is no record upon which to base an estimation of impacts. Commodities and volumes that would be transshipped are not known, let alone the number of U.S. firms (as opposed to foreign firms) that would be affected or the amount by which they might benefit through lower shipping costs or additional temporary storage consignments.

Total estimated receipts of U.S. firms in these industries in 1994 were as follows: ''Deep Sea Foreign Transportation of Freight,'' $8.7 billion; ''Marine Cargo Handling,'' $6.2 billion; ''Scheduled and Nonscheduled Air Transportation,'' $121.5 billion; and ''Airports, Flying Fields, and Airport Terminal Services, $7.6 billion.'' Possible benefits from transshipments at U.S. ports as allowed by this rule change would likely be very slight compared to industry incomes.

**Disposal of Animals**

We are expanding the regulations regarding the disposal of animals, meats, and other articles ineligible for importation to refer to such products affected by African swine fever, swine vesicular disease, hog cholera, and BSE, as well as those products affected by rinderpest and FMD.

This change is expected to have no economic impact. In practice, disposal provisions for animals and meat having African swine fever, hog cholera, swine vesicular disease, or BSE are already the same as for rinderpest or FMD. Specification of these diseases will simply clarify existing provisions.

**Movement of Pork and Pork Products**

We are revising the current import regulations regarding the movement of certain pork and pork products from a port of arrival to an approved U.S. establishment for treatment because of swine vesicular disease, to require that such movement be done under Customs or USDA seal. This change is a clarification to make the regulations in question consistent with similar import requirements with regard to treatment for other diseases. We expect no economic impact from this change, because, currently, there are no such approved establishments in the United States.

**Dry Milk Products**

We are removing the requirement that certain dry milk products intended for importation be processed for human food. The provisions in current § 94.16(b)(2) that require that dry milk products intended for importation from countries in which rinderpest or FMD exists be processed for human food, also require that the dry milk products be processed in a manner approved by the Administrator as adequate to prevent the introduction or dissemination of livestock diseases into the United States. Dry milk products that are processed in a manner adequate to prevent disease can be safely processed for uses other than human food. We expect no increase or decrease in the amount of imported dry milk or dry milk products due to this change, and expect no change in the manner in which such products are processed.

**Casings**

We are removing the requirement that casings imported without certification under § 96.4 be moved to specific cities for disinfection. We expect no economic impact from this change. At present, there are no facilities in any U.S. cities where disinfection of casings is performed, and all casings entering the United States under 9 CFR part 96 are entering in accordance with the certification requirements of § 96.4, which allows the casings to be entered if the casings are accompanied by certification that they were derived from healthy animals that were inspected ante-and post-mortem. In the event of an intended importation of casings that would need to be disinfected in the United States, such disinfection could be done at any facility approved by APHIS.

**Executive Order 12988**

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws 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.

**National Environmental Policy Act**

An environmental assessment and finding of no significant impact have been prepared for this rule. The assessment provides a basis for the conclusion that the actions required or authorized by this rule will not present a significant risk of introducing or disseminating animal disease agents into the United States and will not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*), (2) Regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Copies of the environmental assessment and finding of no significant impact are available for public inspection 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 copies are requested to call ahead on (202) 690–2817 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

**Paperwork Reduction Act**

The information collection burden expected to be imposed by 9 CFR parts 92, 93, and 98 of this rule is 1,809 burden hours for animal importations, which is 176,875 burden hours less than the proposed rule. Although this final rule provides a mechanism for regionalization, it does not assign individual regions to specific risk categories, as did the proposed rule. Because the provisions of the current regulations will continue to be followed

until we receive requests for regionalization, the burden expected is much less than what was expected under the proposed rule. In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection requirements of this final rule have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, we will publish a document in the **Federal Register** providing notice of the assigned OMB control number for parts 92, 93, and 98, or, if approval is denied, providing notice of what action we plan to take.

In accordance with the Paperwork Reduction Act, the information collection or recordkeeping requirements included in this rule under 9 CFR parts 94, 95, and 96 have been approved by the Office of Management and Budget (OMB). The assigned OMB control number is 0579–0015.

This rule contains no new information collection or recordkeeping requirements under 9 CFR parts 97 and 130.

## Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, tribal governments, and the private sector. Under section 202 of the UMRA, APHIS generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rule with ''Federal mandates'' that may result in expenditures by State, local, or tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires APHIS to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective, or least burdensome alternative that achieves the objectives of the rule.

This rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) that may result in expenditures by State, local, and tribal governments, in the aggregate, or to the private sector, or $100 million or more in any one year. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

## List of Subjects

*9 CFR Part 92*

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

*9 CFR Part 93*

Animal diseases, Imports, Reporting and recordkeeping requirements.

*9 CFR Part 94*

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

*9 CFR Part 95*

Animal feeds, Hay, Imports, Livestock, Reporting and recordkeeping requirements, Straw, Transportation.

*9 CFR Part 96*

Imports, Livestock, Reporting and recordkeeping requirements.

*9 CFR Part 97*

Exports, Government employees, Imports, Livestock, Poultry and poultry products, Travel and transportation expenses.

*9 CFR Part 98*

Animal diseases, Imports.

*9 CFR Part 130*

Animals, Birds, Diagnostic reagents, Exports, Imports, Poultry, Quarantine, Reporting and recordkeeping requirements, Tests.

Accordingly, under the authority provided in 5 U.S.C. 5542; 7 U.S.C. 147a, 150ee, 161, 162, 450, 1622, 2260; 19 U.S.C. 1306; 21 U.S.C. 102–105, 111, 114, 114a, 134a, 134b, 134c, 134d, 134f, 135, 136, 136a; 31 U.S.C. 9701; 42 U.S.C. 4331, 4332; 49 U.S.C. 1741; 7 CFR 2.22, 2.80, and 371.2(d), we are amending 9 CFR, chapter I, subchapter D, as follows:

## PART 93—[AMENDED]

### §§ 93.1–93.8 [Redesignated as §§ 93.800–93.807]

1. Part 93 is amended by redesignating §§ 93.1 through 93.8 as §§ 93.800 through 93.807, and designating these sections as Subpart H—Elephants, Hippopotami, Rhinoceroses, and Tapirs.

## PART 92—[REDESIGNATED AS PART 93]

2. In Part 92, subparts A through G (§§ 92.100 through 92.707) are redesignated as part 93, subparts A through G, and part 92 is vacated.

3. A new part 92 is added to read as follows:

## PART 92— IMPORTATION OF ANIMALS AND ANIMAL PRODUCTS: PROCEDURES FOR REQUESTING RECOGNITION OF REGIONS

Sec.
92.1 Definitions.
**92.2 Application for recognition of the animal health status of a region.**

**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).

### § 92.1 Definitions.

*Active surveillance.* Sample collection using a systematic or statistically designed survey methodology to actively seek out and find cases of animals with a restricted disease agent, or to determine the prevalence of the restricted disease agent in the population.

*Adjacent region.* Any geographic land area, whether or not identifiable by geological, political or surveyed boundaries, that shares common boundaries with any region.

*Administrator.* The Administrator of the Animal and Plant Health Inspection Service or any other employee of the Animal and Plant Health Inspection Service, United States Department of Agriculture, delegated to act in the Administrator's stead.

*Animal and Plant Health Inspection Service* (APHIS). The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

*Animals.* All species of the animal kingdom, except man, including: Cattle, sheep, goats, other ruminants, swine, horses, asses, mules, zebras, dogs, poultry, and birds that are susceptible to communicable diseases of livestock and poultry or capable of being carriers of those diseases or their arthropod vectors.

*Communicable disease.* Any contagious or infectious disease of animals. It can be transmitted either directly or indirectly to a susceptible animal from an infected animal, vector, inanimate source, or other sources.

*Contagious disease.* Any communicable disease transmitted from one animal to another by direct contact or by feed, water, aerosol, or contaminated objects.

*Disease agent.* A virus, bacterium, or other organism that causes disease in animals.

*Import (imported, importation) into the United States.* To bring into the territorial limits of the United States.

*Passive surveillance.* A surveillance system that does not depend on active

participation by the responsible agency to seek out and monitor a restricted disease agent. The system relies on mandatory reporting, a pool of trained investigators, diagnostic submission procedures and laboratory support, and periodic public information and continuing education programs on diseases.

*Prevalence*. The number of cases of a disease in existence at a given time in a designated area.

*Region*. Any defined geographic land region identifiable by geological, political or surveyed boundaries. A region may consist of any of the following:

(1) A national entity (country);

(2) Part of a national entity ( zone, county, department, municipality, parish, Province, State, etc.);

(3) Parts of several national entities combined into an area; or

(4) A group of national entities (countries) combined into a single area.

*Restricted disease agent*. Any communicable disease agent or its vector not known to exist in the United States or that is subject to a Federal or cooperative Federal/State control or eradication program within the United States.

*Surveillance*. Systems to find, monitor, and confirm the existence or absence of a restricted disease agent or agents in livestock, poultry and other animals. Surveillance may be passive or active.

*United States*. All of the States of the United States, the District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and all other territories and possessions of the United States.

*Vector-borne disease*. A disease transmitted to an animal through an intermediate arthropod vector, including ticks or insects.

**§ 92.2 Application for recognition of the animal health status of a region.**

(a)(1) The representative of the national government(s) of any country or countries who has the authority to request such a change may request at any time that all or part of the country or countries be recognized as a region, be included within an adjacent previously recognized region, or be made part of a region larger than an individual country. Requests for recognition of a region must be sent to the Administrator, in accordance with paragraph (c) of this section.

(b) Each request for approval to export a particular type of animal or animal product to the United States from a foreign region must be made to the Administrator, in accordance with paragraph (c) of this section, and must include, in English, the following information about the region:

(1) The authority, organization, and infrastructure of the veterinary services organization in the region.

(2) Disease status—i.e., is the restricted disease agent known to exist in the region? If ''yes,'' at what prevalence? If ''no,'' when was the most recent diagnosis?

(3) The status of adjacent regions with respect to the agent.

(4) The extent of an active disease control program, if any, if the agent is known to exist in the region.

(5) The vaccination status of the region. When was the last vaccination? What is the extent of vaccination if it is currently used, and what vaccine is being used?

(6) The degree to which the region is separated from adjacent regions of higher risk through physical or other barriers.

(7) The extent to which movement of animals and animal products is controlled from regions of higher risk, and the level of biosecurity regarding such movements.

(8) Livestock demographics and marketing practices in the region.

(9) The type and extent of disease surveillance in the region—e.g., is it passive and/or active; what is the quantity and quality of sampling and testing?

(10) Diagnostic laboratory capabilities.

(11) Policies and infrastructure for animal disease control in the region—i.e., emergency response capacity.

(c) Requests for recognition of a region or for approval to export animals or animal products to the United States from a region, including the information required by this section, must be sent to the Administrator, c/o National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231. (Where possible, include a copy of the request and accompanying information on a 3.5-inch floppy disk in ASCII or a word processing format.)

(d) The information submitted in accordance with paragraph (b) of this section will be made available to the public prior to initiation by APHIS of any rulemaking action on the request.

(e) If, after review of the information submitted, APHIS believes the requested importation can be safely allowed, APHIS will publish a proposed rule in the **Federal Register** to allow the importation, and the conditions under which the importation would be allowed, along with a discussion of the basis for the proposal.

(f) APHIS will provide a period of time during which the public may comment on the proposal. During the comment period, the public will have access to the information upon which APHIS based its analysis of the risk of such importation, as well as to its methodology in conducting the analysis. Once APHIS has reviewed all comments received, it will make a final decision on what conditions will be necessary to allow the importation in question, and will publish the conditions for import in the **Federal Register**.

4. The heading of part 93 is revised to read as follows:

## PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

5. The authority citation for part 93 is revised 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).

### Subpart A—Birds

6. Newly designated § 93.100 is amended by revising the definition of *Licensed veterinarian* and adding a definition of Region, in alphabetical order, to read as follows:

**§ 93.100 Definitions.**

* * * * *

*Licensed veterinarian*. Any person licensed by any region or political subdivision thereof to practice veterinary medicine.

* * * * *

*Region*. Any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

(1) A national entity (country);

(2) Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.);

(3) Parts of several national entities combined into an area; or

(4) A group of national entities (countries) combined into a single area.

* * * * *

**§ 93.101 [Amended]**

7. Newly designated § 93.101 is amended as follows:

a. In paragraph (a), footnote 1 is amended by removing the word ''countries'' and adding in its place the word ''regions''.

b. By removing the word ''country'' each time it appears and adding in its place each time the word ''region'' in the following places:

i. Paragraph (b)(3)(iii).

ii. Paragraph (b)(3)(v).
iii. Paragraph (b)(3)(vi).
iv. Paragraph (b)(3)(vii).
v. Paragraph (b)(3)(viii).
vi. Paragraph (b)(3)(ix).
vii. Paragraph (b)(3)(x).
viii. Paragraph (b)(3)(xi).
ix. Paragraph (c)(2)(i).
x. Paragraph (c)(2)(ii)(A).
xi. Paragraph (c)(3)(i).
xii. Paragraph (d), introductory text.

c. In paragraph (b)(1), by removing the reference to ''§§ 92.205, 92.214, and 92.216'' and adding in its place a reference to ''§§ 93.205, 93.214, and 93.216''.

d. In paragraph (b)(3), introductory text, by removing the reference to ''§ 92.107'' and adding in its place a reference to ''§ 93.107''.

e. In paragraph (b)(3)(ii), by removing the reference to ''§ 92.103(a)(2)(iv)'' and adding in its place a reference to ''§ 93.103(a)(2)(iv)''.

f. In paragraph (b)(3)(ix), by removing the reference to ''§ 92.103(a)(2)(iv)'' and adding in its place a reference to ''§ 93.103(a)(2)(iv)''.

g. In paragraph (b)(3)(x), by removing the reference to ''§ 92.104(a)'' and adding in its place a reference to ''§ 93.104(a)''.

h. In paragraph (b)(3)(xi), by removing the reference to ''§ 92.104(a)'' and adding in its place a reference to ''§ 93.104(a)''.

i. In paragraph (c)(1), by removing the reference to ''§§ 92.102 or 92.203'' and adding in its place a reference to ''§§ 93.103 or 93.203'', and by removing the reference to ''§ 92.105'' and adding in its place a reference to ''§ 93.105''.

j. In paragraph (c)(2)(i), by removing the reference to ''§ 92.101(c)(1)'' and adding in its place a reference to ''§ 93.101(c)(1)''.

k. In paragraph (c)(3), the introductory text, by removing the reference to ''§ 92.102(a)'' and adding in its place a reference to ''§ 93.102(a)''.

l. In paragraph (c)(3)(ii), by removing the reference to ''§ 92.103(a)(3)'' each time it appears and adding in its place each time a reference to ''§ 93.103(a)(3)'', and by removing the reference to ''§ 92.102(a)'' each time it appears and adding in its place each time a reference to ''93.102(a)''.

m. In paragraph (c)(3)(iv), by removing the reference to ''§ 92.106(a)'' and adding in its place a reference to ''§ 93.106(a)''.

n. In paragraph (c)(3)(v), by removing the reference to ''§ 92.210'' and adding in its place a reference to ''§ 93.210''.

o. In paragraph (d), the introductory text, by removing the reference to ''§ 92.103'' and adding in its place a reference to ''§ 93.103''.

p. In paragraph (d)(1)(ii), by removing the reference to ''§ 92.103(c)'' and adding in its place a reference to ''§ 93.103(c)''.

q. In paragraph (e), by removing the reference to ''§§ 92.102(a), 92.103, 92.104, 92.105(a), and 92.106(a)'' and adding in its place a reference to ''§§ 93.102(a), 93.103, 93.104, 93.105(a), and 93.106(a)''.

r. In paragraph (f), by removing the reference to ''§ 92.102 or 92.203'' and adding in its place a reference to ''§ 93.102 or 93.203'', and by removing the reference to ''§ 92.103'' and adding in its place a reference to ''§ 93.103''.

**§ 93.102 [Amended]**

8. Newly designated § 93.102 is amended as follows:

a. In paragraph (a), by removing the reference to ''§ 92.101(c)'' and adding in its place a reference to ''§ 93.101(c)'', and by removing the reference to ''§ 92.101(f)'' and adding in its place a reference to ''§ 93.101(f)''.

b. In paragraph (c), by removing the reference to ''§ 92.105'' and adding in its place a reference to ''§ 93.105''.

c. In paragraph (d), by removing the reference to ''§ 92.101(c)(1) or (2)'' each time it appears and adding in its place a reference to ''§ 93.101(c)(1) or (2)'', and by removing the reference to ''§ 92.101(f)'' and adding in its place a reference to ''§ 93.101(f)'.

**§ 93.103 [Amended]**

9. Newly designated § 93.103 is amended as follows:

a. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:
i. Paragraph (a)(1)(vi).
ii. Paragraph (a)(1)(viii).
iii. Paragraph (a)(2)(ii), introductory text.
iv. Paragraph (a)(2)(ii)(B).
v. Paragraph (a)(2)(v).
vi. Paragraph (b), second sentence.
vii. Paragraph (c)(1)(ii).
viii. Paragraph (c)(1)(iv).
ix. Paragraph (c)(2)(ii).
x. Paragraph (c)(2)(iv).

b. In paragraph (a)(1), by removing the reference to ''§§ 92.101 (b) and (c), 92.103(c), and 92.107(b)'' and adding in its place a reference to ''§§ 93.101(b) and (c), 93.103(c), and 93.107(b)''.

c. In paragraph (a)(1)(x), by removing the reference to ''§ 92.106(c)(5)'' and adding in its place a reference to ''§ 93.106(c)(5)''.

d. In paragraph (a)(1)(xii), by removing the reference to ''§§ 92.100 through 92.107'' and adding in its place a reference to ''§§ 93.100 through 93.107''.

e. In paragraph (a)(1)(xiii), by removing the reference to ''§ 92.107'' and adding in its place a reference to ''§ 93.107''.

f. In paragraph (a)(2)(i), by removing the reference to ''§ 92.106(c)'' and adding in its place a reference to ''§ 93.106(c)''.

g. In paragraph (a)(2)(iii), by removing the reference to ''§ 92.107'' and adding in its place a reference to ''§ 93.107''.

h. In paragraph (a)(2)(iv), by removing the reference to ''§ 92.107'' and adding in its place a reference to ''§ 93.107''.

i. In paragraph (a)(2)(v), by removing the reference to ''§ 92.101(b)(3)'' each time it appears and adding in its place a reference to ''§ 93.101(b)(3)''.

**§ 93.104 [Amended]**

10. Newly designated § 93.104 is amended as follows:

a. In paragraph (a), by removing the word ''country'' each time it appears and adding in its place the word ''region''.

b. In paragraph (a), by removing the reference to ''§ 92.101 (b) and (c)'' and adding in its place a reference to ''§ 93.101 (b) and (c)''.

c. In paragraph (c)(2), by removing the reference to ''§ 92.107'' and adding in its place a reference to ''§ 93.107''.

d. In paragraph (c)(8), by removing the reference to ''§ 92.107'' and adding in its place a reference to ''§ 93.107''.

e. In paragraph (c)(13), by removing the reference to ''§ 92.101(b)(3)(ix)'' and adding in its place a reference to ''§ 93.101(b)(3)(ix)''.

f. In paragraph (c)(14), by removing the reference to ''§ 92.101(b)(3)'' and adding in its place a reference to ''§ 93.101(b)(3)''.

g. In paragraph (c)(15), by removing the reference to ''§ 92.107'' and adding in its place a reference to ''§ 93.107''.

h. In paragraph (d)(2), by removing the reference to ''§ 92.107'' and adding in its place a reference to ''§ 93.107''.

i. In paragraph (d)(9), by removing the reference to ''§ 92.101(b)(3)(ix)'' and adding in its place a reference to ''§ 93.101(b)(3)(ix)''.

j. In paragraph (d)(10), by removing the reference to ''§ 92.101(b)(3)'' and adding in its place a reference to ''§ 93.101(b)(3)''.

k. In paragraph (d)(11), by removing the reference to ''§ 92.107'' and adding in its place a reference to ''§ 93.107''.

**§ 93.105 [Amended]**

11. Newly designated § 93.105 is amended as follows:

a. In paragraph (a), by removing the reference to ''§ 92.107(c)'' and adding in its place a reference to ''§ 93.107(c)''.

b. In paragraph (b), by removing the reference to ''§ 92.101(c)(2)'' each time it appears and adding in its place a reference to ''§ 93.101(c)(2)''; by removing the reference to ''§ 92.102(a)'' and adding in its place a reference to ''§ 93.102(a)''; and by removing the reference to ''§ 92.102 and 92.203'' and adding in its place a reference to ''§§ 93.102 and 93.203''.

c. In paragraph (c), by removing the reference to ''§ 92.107(b)'' and adding in its place a reference to ''§ 93.107(b)''.

**§ 93.106 [Amended]**

12. Newly designated § 93.106 is amended as follows:

a. In paragraph (c)(5)(iii), the Cooperative and Trust Fund Agreement, the second paragraph, which begins with ''Whereas, the Importer'', by removing the word ''countries'' and adding in its place the word ''regions''.

b. In paragraph (c)(5)(iii), the Cooperative and Trust Fund Agreement, paragraph (B)(5), by removing the word ''country'' and adding in its place the word ''region''.

c. In paragraph (a), by removing the reference to ''§ 92.101(c)'' and adding in its place a reference to ''§ 93.101(c)'', and by removing the reference to ''§ 92.103'' and adding in its place a reference to ''§ 93.103''.

d. In paragraph (b)(1), by removing the reference to ''§ 92.107'' and adding in its place a reference to ''§ 93.107'', and by removing the reference to ''§ 92.103'' and adding in its place a reference to ''§ 93.103''.

e. In paragraph (b)(2), by removing the reference to ''§ 92.107'' and adding in its place a reference to ''§ 93.107''.

f. In paragraph (c)(2)(ii)(L), by removing the reference to ''§ 92.103'' and adding in its place a reference to ''§ 93.103''.

g. In paragraph (c)(2)(ii)(M), by removing the reference to ''§ 92.103'' and adding in its place a reference to ''§ 93.103''.

h. In paragraph (c)(5)(iii), the Cooperative and Trust Fund Agreement, paragraph (A)(4), by removing the reference to ''part 92'' and adding in its place a reference to ''part 93'' each time it appears.

i. In paragraph (c)(5)(iii), the Cooperative and Trust Fund Agreement, paragraph (A)(5), by removing the reference to ''§ 92.106(c)'' and adding in its place a reference to ''§ 93.106(c)''.

j. In paragraph (c)(5)(iii), the Cooperative and Trust Fund Agreement, paragraph (A)(13), by removing the reference to ''§ 92.106(c)(3)(ii)(C)'' and adding in its place a reference to ''§ 93.106(c)(3)(ii)(C)''.

k. In paragraph (c)(5)(iii), the Cooperative and Trust Fund Agreement, paragraph (A)(20), by removing the reference to ''§ 92.106(c)'' and adding in its place a reference to ''§ 93.106(c)''.

l. In subpart A, footnote 13, by removing the reference to ''§ 92.107'' and adding in its place a reference to ''§ 93.107''.

**§ 93.107 [Amended]**

13. Newly designated § 93.107 is amended as follows:

a. In paragraph (a), by removing the reference to ''§ 92.103'' and adding in its place a reference to ''§ 93.103'', and by removing the reference to ''§ 92.101'' and adding in its place a reference to ''§ 93.101''.

b. In paragraph (b)(3), by removing the reference to ''§ 92.203(b)'' and adding in its place a reference to ''§ 93.203(b)''.

c. In paragraph (b)(4), by removing the reference to ''§ 92.104(c)(8)'' and adding in its place a reference to ''§ 93.104(c)(8)''.

d. In paragraph (c)(2), by removing the reference to ''§ 92.105(a)'' and adding in its place a reference to ''§ 93.105(a)''.

e. In paragraph (c)(3), by removing the reference to ''§ 92.203(b)'' and adding in its place a reference to ''§ 93.203(b)''.

## Subpart B—Poultry

14. Newly designated § 93.200 is amended by revising the definition of *Operator* and adding a definition of *Region*, in alphabetical order, to read as follows:

**§ 93.200 Definitions.**

* * * * *

*Operator.* For the purpose of § 93.209, any person operating an approved quarantine facility.

* * * * *

*Region.* Any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

(1) A national entity (country);

(2) Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.)

(3) Parts of several national entities combined into an area; or

(4) A group of national entities (countries) combined into a single area.

* * * * *

**§ 93.201 [Amended]**

15. Newly designated § 93.201 is amended as follows:

a. In paragraph (a), footnote 2, by removing the word ''countries'' and adding in its place the word ''regions''.

b. In paragraph (b), introductory text, by removing the word ''country'' and adding in its place the word ''region''.

c. In paragraph (b), introductory text, by removing the reference to ''part 92'' and adding in its place a reference to ''part 93'', and by removing the reference to ''§ 92.204'' and adding in its place a reference to ''§ 93.204''.

d. In paragraph (b)(1)(ii), by removing the reference to ''§ 92.204(c)'' and adding in its place a reference to ''§ 93.204(c)''.

e. In paragraph (c), by removing the reference to ''§ 92.203'' and adding in its place a reference to ''§ 93.203'', and by removing the reference to ''§ 92.204'' and adding in its place a reference to ''§ 93.204''.

**§ 93.202 [Amended]**

16. In newly designated § 93.202, paragraph (a) is amended by removing the word ''country'' and adding in its place the word ''region''.

**§ 93.204 [Amended]**

17. Newly designated § 93.204 is amended as follows:

a. In paragraph (a)(1), by removing the reference to ''§§ 92.204(c), 92.214, 92.217, and 92.218'' and adding in its place a reference to ''§§ 93.204(c), 93.214, 93.217, and 93.218''.

b. In paragraph (a)(2), by removing the word ''countries'' and adding in its place the word ''regions''.

c. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (a)(1).
ii. Paragraph (a)(2).
iii. Paragraph (b).
iv. Paragraph (c)(1)(iii).
v. Paragraph (c)(1)(v).
vi. Paragraph (c)(2)(ii.)
vii. Paragraph (c)(2)(iv).

**§ 93.205 [Amended]**

18. Newly designated § 93.205 is amended by removing the word ''country'' each time it appears and adding in its place the word ''region''.

**93.207 [Amended]**

19. Newly designated § 93.207 is amended by removing the reference to ''§§ 92.215 and 92.220'' and adding in its place a reference to ''§§ 93.215 and 93.220''.

**§ 93.209 [Amended]**

20. Newly designated § 93.209 is amended as follows:

a. In paragraph (a), by removing the reference to ''§ 92.216'' and adding in its place a reference to ''§ 93.216''.

b. In paragraph (b), by removing the word ''countries'' and adding in its place the word ''regions''.

21. Preceding newly designated § 93.214, in the undesignated center heading ''CANADA [6]'', footnote 6 is amended by removing the reference to ''§§ 92.214 to 92.216'' and adding in its place a reference to ''§§ 93.214 to 93.216''.

**§ 93.214 [Amended]**

22. Newly designated § 93.214 is amended as follows:

a. In paragraph (a), by removing the reference to ''§ 92.204'' and adding in its place a reference to ''§ 93.204'', and by removing the reference to ''§ 92.203(b)'' and adding in its place a reference to ''§ 93.203(b)''.

b. In paragraph (b), by removing the reference to ''§ 92.206'' and adding in its place a reference to ''§ 93.206''.

**§ 93.215 [Amended]**

23. Newly designated § 93.215 is amended as follows:

a. In paragraph (a)(1), by removing the reference to ''§ 92.204'' and adding in its place a reference to ''§ 93.204'', and by removing the reference to ''§ 92.201'' and adding in its place a reference to ''§ 93.201''.

b. In paragraph (b), by removing the word ''country'' and adding in its place the word ''region''.

**§ 93.216 [Amended]**

24. Newly designated § 93.216 is amended by removing the reference to ''§ 92.209'' and adding in its place a reference to ''§ 93.209''.

25. In subpart B, the undesignated heading preceding newly designated § 93.217 is revised to read ''CENTRAL AMERICA AND THE WEST INDIES [7]'', and footnote 7 is amended by removing the reference to ''§ 92.217'' and adding in its place a reference to ''§ 93.217'' and by removing the word ''countries'' and adding in its place the word ''regions''.

**§ 93.217 [Amended]**

26. Newly designated § 93.217 is amended as follows:

a. By removing the word ''countries'' and adding in its place the word ''regions'' in the following places:

i. Paragraph (a).
ii. Paragraph (b).
iii. Paragraph (c).

b. In paragraph (a), by removing the reference to ''§ 92.204'' and adding in its place a reference to ''§ 93.204''.

c. In paragraph (b), by removing the reference to ''§ 92.206'' and adding in its place a reference to ''§ 93.206''.

d. In paragraph (c), by removing the reference to ''§§ 92.205, 92.207, 92.209, and 92.210'' and adding in its place a reference to ''§ 93.205, 93.207, 93.209, and 93.210''.

27. Preceding newly designated § 93.218, in the undesignated center

heading ''MEXICO[8]'', footnote 8 is amended by removing the reference to ''§§ 92.218 to 92.220'' and adding in its place a reference to ''§§ 93.218 to 93.220''.

**§ 93.218 [Amended]**

28. In newly designated § 93.218, paragraph (a) is amended by removing the reference to ''§ 92.204'' and adding in its place a reference to ''§ 93.204''.

**§ 93.219 [Amended]**

29. Newly designated § 93.219 is amended by removing the reference to ''§ 92.206'' and adding in its place a reference to ''§ 93.206''.

**§ 93.220 [Amended]**

30. In newly designated § 93.220, paragraph (b) is amended by removing the reference to ''§ 92.203'' and adding in its place a reference to ''§ 93.203''.

## Subpart C—Horses

31. Newly designated § 93.300 is amended as follows:

a. In the definition of *Code of Practice*, by removing the word ''country'' and adding in its place the word ''region.''

b. By revising the definition of *Licensed veterinarian* and by adding a definition of *Region*, in alphabetical order, to read as follows:

**§ 93.300 Definitions.**

* * * * *

*Licensed Veterinarian*. Any person licensed by any country or political subdivision thereof to practice veterinary medicine.

* * * * *

*Region*. Any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

(1) A national entity (country);

(2) Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.)

(3) Parts of several national entities combined into an area; or

(4) A group of national entities (countries) combined into a single area.

* * * * *

**§ 93.301 [Amended]**

32. Newly designated § 93.301 is amended as follows:

a. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (b), introductory text.
ii. Paragraph (c)(1).
iii. Paragraph (c)(2)(viii).
iv. Paragraph (d)(1)(ii)(E).
v. Paragraph (d)(2).
vi. Paragraph (e)(1), introductory text.
vii. Paragraph (e)(1)(iii).
viii. Paragraph (e)(1)(v).
ix. Paragraph (e)(1)(vi).
x. In the heading of paragraph (g), and introductory text.
xi. Paragraph (g)(1), introductory text.
xii. Paragraph (g)(1)(iii).
xiii. Paragraph (g)(1)(iv).
xiv. Paragraph (h), introductory text.

b. By removing the word ''countries'' each time it appears and adding in its place the word ''regions'' in the following places:

i. Paragraph (a), footnote 3.
ii. Paragraph (c)(1).
iii. In the heading of paragraph (e).
iv. Paragraph (h)(5).

c. In paragraph (b), introductory text, by removing the reference to ''part 92'' and adding in its place a reference to ''part 93'', and by removing the reference to ''§ 92.304'' and adding in its place a reference to ''§ 93.304''.

d. In paragraph (c)(2)(iii), by removing the reference to ''§ 92.314(a)'' and adding in its place a reference to ''§ 93.314(a)''.

e. In paragraph (c)(2)(iv), by removing the reference to ''§ 92.301(a)'' and adding in its place would be removed and a reference to ''§ 93.301(a)''.

f. In paragraph (d)(1)(i), by removing the reference to ''§ 92.304'' and adding in its place a reference to ''§ 93.304''.

g. In paragraph (d)(1)(ii), by removing the reference to ''§ 92.314(a)'' and adding in its place a reference to ''§ 93.314(a)'' each time it appears.

h. In paragraph (d)(3), by removing the reference to ''§ 92.308'' and adding in its place a reference to ''§ 93.308'' each time it appears.

i. In paragraph (e)(1)(i), by removing the reference to ''§ 92.304'' and adding in its place a reference to ''§ 93.304'', and by removing the reference to ''§ 92.308'' and adding in its place a reference to ''§ 93.308''.

j. In paragraph (e)(1)(ii), by removing the reference to ''§ 92.314(a)'' and adding in its place a reference to ''§ 93.314(a)''.

k. In paragraph (e)(2)(i), by removing the reference to ''§ 92.308'' and adding in its place a reference to ''§ 93.308''.

l. In paragraph (f)(1), by removing the reference to ''§ 92.304'' and adding in its place a reference to ''§ 93.304''.

m. In paragraph (f)(4), by removing the reference to ''§ 92.304'' and adding in its place a reference to ''§ 93.304''.

n. In paragraph (f)(6)(i), by removing the reference to ''§ 92.304'' and adding in its place a reference to ''§ 93.304''.

o. In paragraph (g)(1), introductory text, by removing the reference to ''§ 92.314(a)'' and adding in its place a reference to ''§ 93.314(a)''.

p. In paragraph (g)(2), by removing the reference to ''§ 92.304'' and adding in its place a reference to ''§ 93.304''.

q. In paragraph (g)(5), by removing the reference to ''§ 92.308'' and adding in its place a reference to ''§ 93.308''.

**§ 93.302 [Amended]**

33. In newly designated § 93.302, paragraph (a) is amended by removing the word ''country'' and adding in its place the word ''region''.

**§ 93.303 [Amended]**

34. Newly designated § 93.303 is amended as follows:

a. In paragraph (a), by removing the reference to ''§§ 92.308(a), (b), and (c) and 92.317'' and adding in its place a reference to ''§§ 93.308(a), (b), and (c) and 93.317''.

b. In paragraph (e), by removing the reference to ''§§ 92.301(c), 92.304(a), 92.306, 92.308(a), (b), and (c), and 92.314'' and adding in its place a reference to ''§§ 93.301(c), 93.304(a), 93.306, 93.308(a), (b), and (c), and 93.314''.

c. In paragraph (e), by removing the word ''country'' and adding in its place the word ''region'', and in footnote 12, by removing the word ''countries'' and adding in its place the word ''regions''.

**§ 93.304 [Amended]**

35. Newly designated § 93.304 is amended as follows:

a. By removing the word ''countries'' each time it appears and adding in its place the word ''regions'' in the following places:

i. The section heading.
ii. Paragraph (a)(1)(i).
iii. Paragraph (a)(2).

b. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (a)(1)(i).
ii. Paragraph (a)(2).
iii. Paragraph (b)(1).

c. In paragraph (a)(1)(i), by removing the reference to ''§ 92.301(c)(1)'' and adding in its place a reference to ''§ 93.301(c)(1)'', and by removing the reference to ''§§ 92.315, 92.319, and 92.321'' and adding in its place a reference to ''§§ 93.315, 93.319, and 93.321''.

d. In paragraph (a)(1)(ii), introductory text, by removing the reference to ''§ 92.301(f)'' each time it appears and adding in its place a reference to ''§ 93.301(f)''.

e. In paragraph (a)(1)(iii), by removing the reference to ''§ 92.301(f)'' and adding in its place a reference to ''§ 93.301(f)''.

f. In paragraph (a)(2), by removing the reference to ''§ 92.301(c)(1)'' and adding in its place a reference to ''§ 93.301(c)(1)''.

**§ 93.306 [Amended]**

36. In newly designated § 93.306, paragraph (a) is amended by removing the reference to ''§§ 92.318 and 92.323'' and adding in its place a reference to ''§§ 93.318 and 93.323''.

**§ 93.308 [Amended]**

37. Newly designated § 93.308 is amended as follows:

a. In paragraph (a), introductory text, by removing the reference to ''§ 92.324'' and adding in its place a reference to ''§ 93.324'', and by removing the reference to ''§ 92.303'' and adding in its place a reference to ''§ 93.303''.

b. In paragraph (a)(1), by removing the reference to ''§ 92.317'' and adding in its place a reference to ''§ 93.317'', and by removing the reference to ''§ 92.303'' and adding in its place a reference to ''§ 93.303''.

c. In paragraph (a)(2), by removing the word ''countries'' each time it appears and

adding in its place the word ''regions'', and by removing the word ''country and adding in its place the word ''region.''.

d. In paragraph (b), by removing the reference to ''§ 92.303(e)'' and adding in its place a reference to ''§ 93.303(e)''.

e. In paragraph (c)(4)(ii), by removing the reference to ''§ 92.308(a)'' and adding in its place a reference to ''§ 93.308(a)''.

**§ 93.314 [Amended]**

38. Newly designated § 92.314 is amended as follows:

a. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. In paragraph (a), introductory text.

ii. In paragraph (a)(1).

iii. In paragraph (a)(5)(i).

iv. In paragraph (a)(5)(ii).

v. In paragraph (b).

b. In paragraph (a)(5)(iv), by removing the word ''countries'' and adding in its place the word ''regions''.

c. In paragraph (a)(5), introductory text, by removing the reference to ''§ 92.301(g)'' and adding in its place a reference to ''§ 93.301(g)''.

d. In paragraph (a)(5)(i), by removing the reference to ''§ 92.301(c)(1)'' and adding in its place a reference to ''§ 93.301(c)(1)''.

e. In paragraph (c), by removing the reference to reference to ''§ 92.306'' and adding in its place a reference to ''§ 93.306''.

39. Preceding newly designated § 93.315, in the undesignated center heading ''CANADA [16]'', footnote 16 is amended by removing the reference to ''§§ 92.315, 92.316, 92.317 and 92.318'' and adding in its place a reference to ''§§ 93.315, 93.316, 93.317 and 93.318''.

**§ 93.315 [Amended]**

40. Newly designated § 93.315 is amended by removing the reference to ''§ 92.305'' and adding in its place a reference to ''§ 93.305''.

**§ 93.316 [Amended]**

41. Newly designated § 93.316 is amended by removing the reference to ''§ 92.306'' and adding in its place a reference to ''§ 93.306''.

**§ 93.317 [Amended]**

42. In newly designated § 93.317, paragraph (a) is amended by removing the reference to ''§ 92.306'' and adding in its place a reference to ''§ 93.306'', and by removing the reference to ''§ 92.314'' each time it appears and adding in its place a reference to ''§ 93.314''.

**§ 93.318 [Amended]**

43. Newly designated § 93.318 is amended as follows:

a. In paragraph (a)(1), by removing the reference to ''§ 92.304'' and adding in its place a reference to ''§ 93.304'', and by removing the reference to ''§ 92.301'' and adding in its place a reference to ''§ 93.301''.

b. In paragraph (b), by removing the reference to ''§ 92.317(b)'' and adding in its place a reference to ''§ 93.317(b)''.

c. In paragraph (b), by removing the word ''country'' and adding in its place the word ''region''.

44. The undesignated center heading immediately preceding § 93.319 is revised to read ''CENTRAL AMERICA AND THE WEST INDIES [17]'', and footnote 17 is amended by removing word ''countries'' and adding in its place the word ''regions'', and by removing the reference to ''§§ 92.319 and 92.320'' and adding in its place a reference to ''§§ 93.319 and 93.320''.

**§ 93.319 [Amended]**

45. Newly designated § 93.319 is amended by removing the word ''countries'' and adding in its place the word ''regions'', and by removing the reference to ''§ 92.305'' and adding in its place a reference to ''§ 93.305''.

**§ 93.320 [Amended]**

46. Newly designated § 93.320 is amended by removing the reference to ''§ 92.306'' and adding in its place a reference to ''§ 93.306'', by removing the reference to ''§ 92.314'' and adding in its place a reference to ''§ 93.314'', and by removing the reference to ''§ 92.308 (a), (b) and (c)'' and adding in its place a reference to ''§ 93.308 (a), (b), and (c)''.

47. Preceding newly designated § 93.321, in the undesignated center heading ''MEXICO [18]'', footnote 18 is amended by removing the reference to ''§§ 92.321 to 92.326'' and adding in its place a reference to ''§§ 93.321 to 93.326''.

**§ 93.322 [Amended]**

48. Newly designated § 93.322 is amended by removing the reference to ''§ 92.305'' and adding in its place a reference to ''§ 93.305''.

**§ 93.323 [Amended]**

49. In newly designated § 93.323, paragraphs (a) and (b) are amended by removing the references to ''§ 92.324'' and adding in their place a reference to ''§ 93.324''.

**§ 93.324 [Amended]**

50. Newly designated § 93.324 is amended by removing the reference to ''§ 92.303(a)'' and adding in its place a reference to ''§ 93.303(a)''.

**§ 93.325 [Amended]**

51. Newly designated § 93.325 is amended by removing the reference to ''§§ 92.306 and 92.323'' and adding in its place a reference to ''§§ 93.306 and 93.323'', by removing the reference to ''§ 92.314'' and adding in its place a reference to ''93.314'', and by removing the reference to ''§ 92.324'' and adding in its place a reference to ''§ 93.324''.

**§ 93.326 [Amended]**

52. Newly designated § 93.326 is amended by removing the reference to ''§§ 92.321, 92.322, 92.323, and 92.324'' and adding in its place a reference to ''§§ 93.321, 93.322, 93.323, and 93.324'', and by removing the words ''in § 92.324'' and adding in their place the words ''in § 93.324''.

## Subpart D—Ruminants

53. In newly designated § 93.400, the definition of *Brucellosis certified free province and territories of Canada* is revised, and a new definition of *Region* is added, in alphabetical order, to read as follows:

**§ 93.400 Definitions.**

* * * * *

*Brucellosis certified-free province or territory of Canada.* A province or territory of Canada in which all herds of cattle are brucellosis certified free. The brucellosis certified free provinces and territories of Canada are Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland (including Labrador), Northwest Territories, Nova Scotia, Ontario, Quebec, Prince Edward Island, Saskatchewan, and Yukon Territory.

* * * * *

*Region.* Any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

(1) A national entity (country);

(2) Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.);

(3) Parts of several national entities combined into an area; or

(4) A group of national entities (countries) combined into a single area.

* * * * *

**§ 93.401 [Amended]**

54. Newly designated § 93.401 is amended as follows:

a. In paragraph (a), footnote 3, by removing the word ''countries'' and adding the word ''regions'' in its place;

b. In paragraph (b), introductory text, by removing the word ''country'' and adding the word ''region'' in its place, and by removing the reference to ''§ 92.404'' and adding in its place a reference to ''§ 93.404''.

**§ 93.402 [Amended]**

55. In newly designated § 93.402, paragraph (a) is amended by removing the word ''country'' and adding the word ''region'' in its place.

**§ 93.403 [Amended]**

56. In newly designated § 93.403, paragraph (g), the references to

''§§ 92.401, 92.404(a), 92.407, 92.408, 92.433, and 92.434'' are removed, and references to ''§§ 93.401, 93.404(a), 93.407, 93.408, 93.433, and 93.434'' are added in their place.

**§ 93.404 [Amended]**

57. Newly designated § 93.404 is amended as follows:

a. In paragraph (a)(1), by removing the reference to ''§§ 92.417, 92.422, and 92.424'' and adding in its place a reference to ''§§ 93.417, 93.422, and 93.424''.

b. In paragraph (a)(2), by removing the reference to ''§ 92.430'' and adding in its place a reference to ''§ 93.430''.

c. In paragraph (c)(4), ''Agreement for the Importation, Quarantine and Exhibition of Certain Wild Ruminants and Wild Swine'', paragraph 2, the first sentence, by removing the words ''this country'' and adding in their place the words ''the United States''.

d. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (a)(1).

ii. Paragraph (a)(2).

iii. Paragraph (a)(3).

iv. Paragraph (b).

v. Paragraph (c)(4), in the ''Agreement for the Importation, Quarantine and Exhibition of Certain Ruminants and Swine'', in the introductory text and in paragraph (1) and paragraph (2).

e. By removing the word ''countries'' each time it appears and adding in its place the word ''regions'' in the following places:

i. Paragraph (a)(3).

ii. Paragraph (c), the heading and the introductory text.

f. In paragraph (c)(4), the ''Agreement for the Importation, Quarantine and Exhibition of Certain Ruminants and Swine'', introductory text, by removing the reference to ''part 92'' and adding in its place a reference to ''part 93''.

**§ 93.405 [Amended]**

58. Newly designated § 93.405 is amended as follows:

a. In paragraph (a), by removing the reference to ''§§ 92.418(a), 92.419(a), 92.423(c), and 92.428(d)'' and adding in its place a reference to ''§§ 93.418(a), 93.419(a), 93.423(c), and 93.428(d)''.

b. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (a), introductory text.

ii. Paragraph (a)(1).

iii. Paragraph (a)(2).

iv. Paragraph (c)(3).

c. In paragraph (b)(2)(ii), by removing the reference to ''§ 92.435(a)'' and adding in its place a reference to ''§ 93.435(a)''.

d. In paragraph (c)(3), by removing the reference to ''§ 92.435(a)'' and adding in its place a reference to ''§ 93.435(a)''.

**§ 93.406 [Amended]**

59. Newly designated § 93.406 is amended as follows:

a. In paragraph (a), by removing the reference to ''§§ 92.418, 92.427(c) and (d), and 92.432'' and adding in its place a reference to ''§§ 93.418, 93.427(c) and (d), and 93.432'', and by removing the word ''country'' and adding the word ''region'' in its place.

b. In paragraph (b), by removing the reference to ''§§ 92.419 and 92.428(b)'' and adding in its place a reference to ''§§ 93.419 and 93.428(b),'' and by removing the word ''country'' and adding in its place the word ''region'.

c. In paragraph (c), by removing the reference to ''§ 92.411'' and adding in its place a reference to ''§ 93.411''.

**§ 93.408 [Amended]**

60. Newly designated § 93.408 is amended by removing the reference to ''§§ 92.421 and 92.426'' and adding in its place a reference to ''§§ 93.421 and 93.426'', and by removing the reference to ''§§ 92.423(c) and 92.427(a)'' and adding in its place a reference to ''§§ 93.423(c) and 93.427(a)''.

61. Preceding newly designated § 93.417, in the undesignated center heading ''CANADA [7]'', footnote 7 is amended by removing the reference to ''§§ 92.417 to 92.421'' and adding in its place a reference to ''§§ 93.417 to 93.421''.

**§ 93.417 [Amended]**

62. Newly designated § 93.417 is amended as follows:

a. In paragraph (a), introductory text, by removing the reference to ''§ 92.404'' and adding in its place a reference to ''§ 93.404'', and by removing the reference to ''§ 92.403(b)'' and adding in its place a reference to ''§ 93.403(b)''.

b. In paragraph (a)(3)(i) and paragraph (a)(3)(ii), by removing the word ''country'' and adding in its place the word ''region'.

c. In paragraph (b), by removing the reference to ''§ 92.407'' and adding in its place a reference to ''§ 93.407''.

63. Newly designated § 93.418 is amended as follows:

a. In paragraph (a), by removing the reference to ''§ 92.420'' and adding in its place a reference to ''§ 93.420'', and by removing the reference to ''§ 92.405(a)'' and adding in its place a reference to ''§ 93.405(a)'.

b. In paragraph (b)(2)(i), by removing the reference to ''§ 92.420'' and adding in its place a reference to ''§ 93.420''.

c. By revising paragraph (c) to read as set forth below.

d. In paragraph (d)(4), by removing the reference to ''paragraph (c)(5)'' and adding in its place a reference to ''paragraph (c)(2)(ii)(C)''.

**§ 93.418 Cattle from Canada.**

* * * * *

(c) *Brucellosis test or vaccination certificates.* (1) Cattle from Canada from a herd in which any cattle have been determined to have brucellosis may not be imported into the United States;

(2) Except for cattle prohibited from importation into the United States under paragraph (c)(1) of this section, cattle 6 months of age or older from Canada may be imported into the United States if the following conditions are met:

(i) The cattle are imported for slaughter in accordance with § 92.420;

(ii) The cattle are steers; or

(iii) The cattle are accompanied by a certificate issued or endorsed by a salaried veterinarian of the Canadian government showing:

(A) That the cattle are from a brucellosis certified-free herd, province, or territory; or

(B) The date and place the cattle were last tested for brucellosis; that the cattle were found negative for brucellosis on such test; and that such test was performed within 30 days preceding the arrival of the cattle at the port of entry; or

(C) That the female cattle under 18 months of age were vaccinated against brucellosis in accordance with Canadian regulations.

* * * * *

**§ 93.419 [Amended]**

64. In newly designated § 93.419, paragraph (a) is amended by removing the reference to ''§ 92.420'' and adding in its place a reference to § 93.420''; and by removing the reference to ''§ 92.405'' and adding in its place a reference to ''§ 93.405''.

**§ 93.420 [Amended]**

65. Newly designated § 92.420 is amended by removing the reference to ''§ 92.408'' and adding in its place a reference to ''§ 93.408''.

**§ 93.421 [Amended]**

66. Newly designated § 93.421 is amended as follows:

a. In paragraph (a)(1), by removing the reference to ''§ 92.404'' and adding in its place a reference to ''§ 93.404'', and by removing the reference to ''§ 92.401'' and adding in its place a reference to ''§ 93.401''.

b. In paragraph (b), by removing the word ''country'' and adding in its place the word ''region''.

67. Preceding newly designated § 93.422, the undesignated center heading ''COUNTRIES OF CENTRAL AMERICA AND WEST INDIES[8]'' is revised to read ''CENTRAL AMERICA AND WEST INDIES[8]'', and footnote 8 is amended by removing the word ''countries'' and adding in its place the word ''regions'', and by removing the reference to ''§§ 92.422 and 92.423'' and adding in its place a reference to ''§§ 93.422 and 93.423''.

**§ 93.422 [Amended]**

68. Newly designated § 93.422 is amended as follows:

a. In paragraph (a), by removing the reference to ''§ 92.404'' and adding in its place a reference to ''§ 93.404'', and by removing the reference to ''§ 92.423'' and adding in its place a reference to ''§ 93.423''.

b. In paragraph (b), by removing the reference to ''§ 92.407'' and adding in its place a reference to ''§ 93.407''.

69. In newly designated § 93.422, paragraphs (a) and (b) are amended by removing the word ''countries'' and adding in its place the word ''regions''.

**§ 93.423 [Amended]**

70. Newly designated § 93.423 is amended as follows:

a. In paragraph (a), by removing the word ''country'' each time it appears and adding in its place the word ''region''; by removing the reference to ''§ 92.405(a)'' and adding in its place a reference to ''§ 93.405(a)''; and by removing the reference to ''§ 92.420'' and adding in its place a reference to ''§ 93.420''.

b. In paragraph (b), by removing the reference to ''§ 92.405'' and adding in its place a reference to ''§ 93.405''.

c. In paragraph (c), by removing the reference to ''§ 92.403(d)'' and adding in its place a reference to ''§ 93.403(d)''.

71. Preceding newly designated § 93.424, in the undesignated center heading ''MEXICO [9]'', footnote 9 is amended by removing the reference to ''§§ 92.424 to 92.429,'' and adding in its place a reference to ''§§ 93.424 to 93.429''.

**§ 93.424 [Amended]**

72. Newly designated ''§ 93.424'' is amended as follows:

a. In paragraph (a), introductory text, by removing the reference to ''§ 92.404'' and adding in its place a reference to ''§ 93.404''; and by removing the reference to ''§ 92.403(c)'' and adding in its place a reference to ''§ 93.403(c)''.

b. In paragraph (a)(3)(i) and paragraph (a)(3)(ii), by removing the word ''country'' each time it appears and adding in its place the word ''region''.

c. In paragraph (a)(3)(iii), by removing the word ''countries'' and adding in its place the word ''regions''.

d. In paragraph (b), by removing the reference to ''§ 92.427(d)'' each time it appears and adding in its place a reference to ''§ 93.427(d)''.

**§ 93.425 [Amended]**

73. Newly designated § 93.425 is amended by removing the reference to ''§ 92.407'' and adding in its place a reference to ''§ 93.407''.

**§ 93.426 [Amended]**

74. Newly designated § 93.426 is amended as follows:

a. In paragraph (a), by removing the reference to ''§ 92.427'' and adding in its place a reference to ''§ 93.427''.

b. In paragraph (b), by removing the reference to ''§ 92.403'' and adding in its place a reference to ''§ 93.403''.

**§ 93.427 [Amended]**

75. Newly designated § 93.427 is amended as follows:

a. By removing the reference to ''§ 92.405(a)'' and adding in its place a reference to § 93.405(a) in the following places:

i. Paragraph (b)(1).

ii. Paragraph (b)(2)(i).

iii. Paragraph (b)(2)(ii).

iv. Paragraph (c)(1).

v. Paragraph (d)(1), introductory text.

b. In paragraph (b)(2), introductory text, by removing the reference to ''§ 92.403(c)'' and adding in its place a reference to ''§ 93.403(c)''.

c. In paragraph (c)(1), by removing the word ''country's'' and adding in its place the word ''region's''.

d. In paragraph (c)(1) and paragraph (c)(2), by removing the reference to ''§ 92.429'' each time it appears and adding in its place a reference to ''§ 93.429''.

e. In paragraph (c)(2), by removing the reference to ''§ 92.427(e)'' and adding in its place a reference to ''§ 93.427(e)''.

**§ 93.428 [Amended]**

76. Newly designated § 93.428 is amended as follows:

a. In paragraph (a), by removing the reference to ''§ 92.405'' and adding in its place a reference to ''§ 93.405'', and by removing the reference to ''§ 92.427(a)'' and adding in its place a reference to ''§ 93.427(a)''.

b. In paragraph (b), by removing the reference to ''§ 92.427'' and adding in its place a reference to ''§ 93.427''.

c. In paragraph (d), by removing the reference to ''§ 92.426'' and adding in its place a reference to ''§ 93.426''.

**§ 93.429 [Amended]**

77. Newly designated § 93.429 is amended by removing the reference to ''§§ 92.424, 92.425, 92.426, and 92.427(b)(2)'' and adding in its place a reference to ''§§ 93.424, 93.425, 93.426, and 93.427(b)(2)'', and by removing the reference to ''§ 92.405(a)'' and adding in its place a reference to ''§ 93.405(a)''.

**§ 93.430 [Amended]**

78. Newly designated § 92.430 is amended as follows:

a. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (c)(1).

ii. Paragraph (d), ''Cooperative Services Agreement Between (Name of Importer) and the United States Department of Agriculture, Animal and Plant Health Inspection Service'', under ''The importer agrees:'', paragraph 4.

iii. Paragraph (d), ''Cooperative Services Agreement Between (Name of Importer) and the United States Department of Agriculture, Animal and Plant Health Inspection Service'', under ''Both parties agree:'', paragraph 4.

b. In paragraph (d), ''Cooperative Services Agreement Between (Name of Importer) and the United States Department of Agriculture, Animal and Plant Health Inspection Service'', under ''The importer agrees:'', paragraph 7, by removing the reference to ''9 CFR 92.431'' and adding in its place a reference to ''9 CFR 93.431''.

**§ 93.431 [Amended]**

79. Newly designated § 93.431 is amended as follows:

a. In paragraph (a)(4), by removing the reference to ''§ 92.430(d)'' both times it appears and adding in its place a reference to ''§ 93.430(d)''.

b. In paragraph (b)(2)(iv) and paragraph (b)(4), by removing the word ''country'' and adding in its place the word ''region''.

**§ 93.432 [Amended]**

80. Newly designated § 93.432 is amended as follows:

a. In paragraph (a), by removing the reference to ''§ 92.432(c)'' and adding in its place a reference to ''§ 93.432(c)''.

b. In paragraph (b)(2), introductory text, by removing the reference to ''§ 92.432(c)(1)'' and adding in its place a reference to ''§ 93.432(c)(1)''.

**§ 93.434 [Amended]**

81. Newly designated § 93.434 is amended as follows:

a. In paragraph (a) and the introductory text of paragraph (b), by removing the reference to ''§ 92.412'' each time it appears and adding in its place a reference to ''§ 93.412''.

b. In paragraph (b)(2)(i)(A), by removing the reference to ''§ 92.403(g)'' and adding in its place a reference to ''§ 93.403(g)''.

**§ 93.435 [Amended]**

82. Newly designated § 93.435 is amended as follows:

a. In paragraph (b)(2), by removing the reference to ''§ 92.405(b)(2)(ii)'' and adding in its place a reference to ''§ 93.405(b)(2)(ii)''.

b. By removing the word ''country'' and adding in its place the word ''region'' in the following places:

i Paragraphs (b)(2) and (b)(3).

ii. Paragraph (d).

iii. Paragraph (e).

iv. Paragraph (g)(2)(i) and (g)(2)(ii).

c. In paragraph (b)(3), by removing the reference to ''§ 92.405(c)(3)'' and adding in its place a reference to ''§ 93.405(c)(3)''.

d. In paragraph (b)(6), by removing the reference to ''§ 92.404(c)'' and adding in its place a reference to ''§ 93.404(c)''.

## Subpart E—Swine

83. Newly designated 93.500 is amended by adding a definition of

*Region*, in alphabetical order, to read as follows:

**§ 93.500 Definitions.**

* * * * *

*Region*. Any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

(1) A national entity (country);

(2) Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.);

(3) Parts of several national entities combined into an area; or

(4) A group of national entities (countries) combined into a single area.

* * * * *

**§ 93.501 [Amended]**

84. In newly designated § 93.501, paragraph (b), the introductory text is amended by removing the reference to ''part 92'' and adding in its place a reference to ''part 93''; by removing the word ''country'' and adding in its place the word ''region''; and by removing the reference to ''§ 92.504'' and adding in its place a reference to ''§ 93.504''.

**§ 93.502 [Amended]**

85. In newly designated § 93.502, paragraph (a) is amended by removing the word ''country'' and adding in its place the word ''region''.

**§ 93.504 [Amended]**

86. Newly designated § 93.504 is amended as follows:

a. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (a)(1).

ii. Paragraph (a)(2).

iii. Paragraph (a)(3).

iv. Paragraph (b).

v. Paragraph (c)(4), ''Agreement for the Importation, Quarantine and Exhibition of Certain Wild Ruminants and Wild Swine'', in the introductory text, paragraph (1), and paragraph (2).

b. In paragraph (a)(1), by removing the reference to ''§§ 92.516 and 92.520'' and adding in its place a reference to ''§§ 93.516 and 93.520''.

c. In paragraph (a)(2), by removing the reference to ''§ 92.522'' and adding in its place a reference to ''§ 93.522''.

d. By removing the word ''countries'' and replacing it with the word ''regions'' in the following places:

i. Paragraph (a)(3).

ii. Paragraph (c) in the heading and in the introductory text.

e. In paragraph (c)(4), ''Agreement for the Importation, Quarantine and Exhibition of Certain Wild Ruminants and Wild Swine, introductory text, by removing the reference to ''part 92'' and adding in its place a reference to ''part 93''.

**§ 93.505 [Amended]**

87. In newly designated § 93.505, paragraph (a) is amended by removing the reference to § 92.517'' and adding in its place a reference to ''§ 93.517'', and by removing the word ''country'' each time it appears and adding in its place the word ''region'.

**§ 93.507 [Amended]**

88. Newly designated § 93.507 is amended by removing the reference to ''§ 92.519'' and adding in its place a reference to ''§ 93.519''.

89. Preceding newly designated § 93.516, in the undesignated center heading ''CANADA[7]'', footnote 7 is amended by removing the reference to ''§§ 92.516 to 92.519'' and adding in its place a reference to ''§§ 93.516 to 93.519''.

**§ 93.516 [Amended]**

90. Newly designated § 93.516 is amended as follows:

a. In paragraph (a), introductory text, by removing the reference to ''§ 92.504'' and adding in its place a reference to ''§ 93.504'', and by removing the reference to ''§ 92.503(b)'' and adding in its place a reference to ''§ 93.503(b)''.

b. In paragraph (a)(1) and paragraph (a)(2), by removing the word ''country'' each time it appears and adding in its place the word ''region''.

c. In paragraph (b), by removing the reference to ''§ 92.506'' and adding in its place a reference to ''§ 93.506''.

**§ 93.517 [Amended]**

91. In newly designated § 93.517, paragraph (b) is amended by removing the reference to § 92.507, 92.516, and 92.518'' and adding in its place a reference to ''§§ 93.507, 93.516, and 93.518''.

**§ 93.519 [Amended]**

92. Newly designated § 93.519 is amended as follows:

a. In paragraph (a)(1), by removing the reference to ''§ 92.504'' and adding in its place a reference to ''§ 93.504'', and by removing the reference to ''§ 92.501'' and adding in its place a reference to ''§ 93.501''.

b. In paragraph (b), by removing the word ''country'' and adding in its place the word ''region''.

93. Preceding newly designated § 93.520, the undesignated center heading ''COUNTRIES OF CENTRAL AMERICA AND WEST INDIES[8]'' is revised to read ''CENTRAL AMERICA AND WEST INDIES[8]'', and footnote 8 is amended by removing the word ''countries'' and adding in its place the word ''regions'', and by removing the reference to ''§§ 92.520 to 92.522'' and adding in its place a reference to ''§§ 93.520 to 93.522.''

**§ 93.520 [Amended]**

94. Newly designated § 93.520 is amended by removing the reference to ''§ 92.506'' and adding in its place a reference to ''§ 93.506''.

95. Preceding newly designated § 93.521, in the undesignated center heading ''MEXICO[9]'', footnote 9 is amended by removing the reference to ''§ 92.521'' and adding in its place a reference to ''§ 93.521''.

**§ 93.521 [Amended]**

96. Newly designated § 93.521 is amended by removing the reference to ''§ 92.506'' and adding in its place a reference to ''§ 93.506''.

**§ 93.522 [Amended]**

97. Newly designated § 93.522 is amended as follows:

a. In paragraph (c)(1), by removing the words ''country or area'' and adding in their place the word ''region''.

b. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (c)(3).

ii. Paragraph (d), ''Cooperative-Services Agreement Between (Name of Importer) and the United States Department of Agriculture, Animal and Plant Health Inspection Service'', under ''The importer agrees:'', paragraph 4.

iii. Paragraph (d), ''Cooperative-Services Agreement Between (Name of Importer) and the United States Department of Agriculture, Animal and Plant Health Inspection Service'', under ''Both parties agree:'', paragraph 4.

c. In paragraph (d), ''Cooperative-Services Agreement Between (Name of Importer) and the United States Department of Agriculture, Animal and Plant Health Inspection Service'', under ''The importer agrees:'', paragraph 7, by removing the reference to ''§ 92.523'' and adding in its place a reference to ''§ 93.523''.

**§ 93.523 [Amended]**

98. Newly designated § 93.523 is amended as follows:

a. In paragraph (a)(4), by removing the reference to ''§ 92.522(d)'' both times it appears and adding in its place a reference to ''§ 93.522(d)''.

b. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (b)(2)(iv).

ii. Paragraph (b)(2)(viii).

iii. Paragraph (b)(4)

## Subpart F—Dogs

**§ 93.600 [Amended]**

99. Newly designated § 93.600 is amended by removing the word ''countries'' and adding in its place the word ''regions''.

## Subpart G—Miscellaneous Animals

100. In newly designated § 93.700, a definition of *Region* is added, in alphabetical order, to read as follows:

### § 93.700 Definitions.

* * * * *

*Region.* Any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

(1) A national entity (country);

(2) Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.)

(3) Parts of several national entities combined into an area; or

(4) A group of national entities (countries) combined into a single area.

* * * * *

### § 93.701 [Amended]

101. Newly designated § 93.701 is amended by removing the word ''country'' both times it appears and adding in its place the word ''region'.

### § 93.702 [Amended]

102. Newly designated § 93.702 is amended by removing the reference to ''§ 92.701'' and adding in its place a reference to ''§ 93.701''.

### § 93.704 [Amended]

103. Newly designated § 93.704 is amended by removing the word ''country'' each time it appears and adding in its place the word ''region'' in the paragraph (c)(1) and paragraph (c)(4).

### § 93.705 [Amended]

104. Newly designated § 93.705 is amended by removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

a. Paragraph (a), introductory text.
b. Paragraph (a)(1).
c. Paragraph (a)(2).
d. Paragraph (a)(3).

## Subpart H—Elephants, Hippopotami, Rhinoceroses, and Tapirs

105. Newly designated § 93.800 is amended by adding a definition of *Region,* in alphabetical order, to read as follows:

### § 93.800 Definitions.

* * * * *

*Region.* Any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

(1) A national entity (country);

(2) Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.)

(3) Parts of several national entities combined into an area; or

(4) A group of national entities (countries) combined into a single area.

* * * * *

### § 93.803 [Amended]

106. In newly designated § 93.803, paragraph (a), the introductory text is amended by removing the word ''country'' each time it appears and adding in its place the word ''region'.

### § 93.804 [Amended]

107. In newly designated § 93.804, paragraph (g) is amended by removing the word ''country'' and adding in its place the word ''region''.

## PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

108. The authority citation for part 94 continues to read as follows:

**Authority:** 7 U.S.C. 147a, 150ee, 161, 162, 450; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, 134f, 136, and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.2(d).

109. In § 94.0, the definition of *Country of origin* is removed and definitions of *Cervid, Contact, Pink juice test, Region, Region of origin, Ruminants, and Veterinarian in charge* are added, in alphabetical order, to read as follows:

### § 94.0 Definitions.

* * * * *

*Cervid.* All species of deer, elk, and moose.

* * * * *

*Contact.* Known or potential commingling of products during processing or storage, or while being transported from any point to any other point. Contact includes the simultaneous processing in the same room, locker, or container, but not necessarily the same storage facility or conveyance, as long as adequate security measures are taken to prevent commingling, as determined by an authorized APHIS representative.

* * * * *

*Pink juice test.* Determination of whether meat has been thoroughly cooked by observation of whether the flesh and juices have lost all red and pink color.

* * * * *

*Region.* Any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

(1) A national entity (country);

(2) Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.)

(3) Parts of several national entities combined into an area; or

(4) A group of national entities (countries) combined into a single area.

*Region of origin.* For meat and meat products, the region in which the animal from which the meat or meat products were derived was born, raised and slaughtered; and for eggs, the region in which the eggs were laid.

*Ruminants.* All animals that chew the cud, such as cattle, buffaloes, sheep, goats, deer, antelopes, camels, llamas and giraffes.

* * * * *

*Veterinarian in Charge.* The veterinary official of the Animal and Plant Health Inspection Service, United States Department of Agriculture, who is assigned by the Administrator to supervise and perform the official animal health work of the Animal and Plant Health Inspection Service in the State or area concerned.

* * * * *

### § 94.1 [Amended]

110. Section 94.1 is amended as follows:

a. By removing the word ''Countries'' in the heading to the section and adding in its place the word ''Regions''.

b. By removing the word ''countries'' each time it appears and adding in its place the word ''regions'' in the following places:

i. Paragraph (a)(1);
ii. Paragraph (a)(2);
iii. Paragraph (b).

c. By removing the words ''fresh, chilled, or frozen'' each time they appear and adding in their place the words ''fresh (chilled or frozen)'' in paragraph (b) and paragraph (c).

d. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (b).
ii. Paragraph (c), introductory text.
iii. Paragraph (c)(2).
iv. Paragraph (c)(3).
v. Paragraph (c)(5).

### § 94.1a [Amended]

111. Section 94.1a is amended as follows:

a. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (a), introductory text.
ii. Paragraph (a)(2).
iii. Paragraph (a)(7).
iv. Paragraph (a)(8), introductory text.

b. In paragraph (a)(7) and in paragraph (a)(8), introductory text, by removing the word ''countries'' each time it appears and adding in its place the word ''regions''.

**§ 94.2 [Amended]**

112. Section 94.2 is amended as follows:

a. In the heading to the section, by removing the words ''Fresh, chilled, or frozen'' and adding in their place the words ''Fresh (chilled or frozen)'';

b. In paragraph (a), by removing the words ''fresh, chilled, or frozen'' and adding in their place the words ''fresh (chilled or frozen)''.

c. In paragraphs (a) and (b), by removing the word ''country'' each time it appears and adding in its place the word ''region''.

**§ 94.3 [Amended]**

113. Section 94.3 is amended by removing the words ''fresh, chilled, or frozen'' and adding in their place the words ''fresh (chilled or frozen)'' and by removing the word ''country'' and adding in its place the word ''region''.

**§ 94.4 [Amended]**

114. Section 94.4 is amended as follows:

a. In the heading to the section, by removing the word ''countries'' and adding in its place the word ''regions''.

b. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (a), introductory text.
ii. Paragraph (a)(1).
iii. Paragraph (a)(4).
iv. Paragraph (b), introductory text.
v. Paragraph (b)(7).
vi. Paragraph (c)(1)(iii).
vii. Paragraph (c)(2)(iv).

**§ 94.5 [Amended]**

115. In § 94.5, paragraph (b)(1)(i)(A) is amended by removing the word ''country'' and adding the word ''region'' in its place, and by removing the word ''countries'' and adding the word ''regions'' in its place.

**§ 94.6 [Amended]**

116. Section 94.6 is amended as follows:

a. By removing the word ''countries'' each time it appears and adding in its place the word ''regions'' in the following places:

i. The heading to the section.
ii. Paragraphs (a)(1) and (a)(2).
iii. Paragraph (b)(1).
iv. Paragraph (b)(2).
v. The heading to paragraph (c).
vi. The heading to paragraph (d).

b. In the heading to paragraph (a) and in the heading to paragraph (b), by removing the word ''Countries'' each time it appears and adding in its place the word ''Regions''.

c. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (c), introductory text.
ii. Paragraph (d), introductory text.
iii. Paragraph (d)(1), introductory text.
iv. Paragraph (d)(1)(i).
v. Paragraph (d)(1)(iii).
vi. Paragraph (d)(1)(v).
vii. Paragraph (d)(1)(viii).
viii. Paragraph (d)(1)(ix), introductory text.
ix. Paragraph (d)(1)(ix)(C)(*1*).
x. Paragraph (d)(1)(ix)(C)(*2*).
xi. Paragraph (d)(1)(x), introductory text.
xii. Paragraph (d)(1)(x)(C)(*1*).
xiii. Paragraph (d)(1)(x)(C)(*2*).
xiv. Paragraph (d)(1)(x)(C)(*3*).

**§ 94.7 [Amended]**

117. Section 94.7 is amended as follows:

a. By removing the words ''fresh, chilled, or frozen'' wherever they appear and adding in their place the words ''fresh (chilled or frozen)'' in the following places:

i. Paragraph (a);
ii. Paragraph (b);
iii. Paragraph (c);
iv. Paragraph (d).

b. By removing the reference to ''§ 94.1,'' each time it appears and adding in its place a reference to ''§§ 94.1, 94.8, 94.9, 94.10, 94.12, 94.14, or 94.18,'' in the following places:

i. Paragraph (a).
ii. Paragraph (b).
iii. Paragraph (c).
iv. Paragraph (d).

**§ 94.8 [Amended]**

118. Section 94.8 is amended as follows:

a. In paragraph (a)(3)(iv)(A), by removing the words ''countries or parts of countries'' and adding in their place the word ''regions''.

b. In the heading to the section, by removing the word ''countries'' and adding in its place the word ''regions''.

c. In footnote 7, before paragraph (1), by removing the words ''country or a part of a country'' and adding in their place the word ''region'', and, in paragraph (4), by removing the words ''this country'' and adding in their place the words ''the United States''.

d. By removing the words ''country or part of a country'' and adding in their place the word ''region'' in the following places:

i. Paragraph (a), introductory text.
ii. Paragraph (a)(3)(i)(A).
iii. Paragraph (a)(3)(i)(B).
iv. Paragraph (a)(3)(v).
v. Paragraph (c).

e. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places.

i. Footnote 7 to the introductory text of the section.
ii. Paragraph (a)(3)(i)(B).
iii. Paragraph (a)(3)(i)(C).
iv. Paragraph (a)(3)(i)(D).
v. Paragraph (a)(3)(vi).

f. In footnote 7 to the introductory text of the section, by removing the word ''country's'' and adding in its place the word ''region's''.

**§ 94.9 [Amended]**

119. Section 94.9 is amended as follows:

a. By removing the word ''countries'' each time it appears and adding in its place the word ''regions'' in the following places:

i. The heading to the section.
ii. Paragraph (a), introductory text.
iii. Paragraph (b)(1)(iii)(C)(*2*).
iv. Paragraph (c).

b. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (b), introductory text.
ii. Paragraph (b)(1)(ii)(A).
iii. Paragraph (b)(1)(iii)(A).
iv. Paragraph (b)(1)(iii)(C), introductory text.
v. Paragraph (b)(1)(iii)(C)(*1*).
vi. Paragraph (b)(1)(iii)(C)(*2*).
vii. Paragraph (b)(3).

**§ 94.10 [Amended]**

120. Section 94.10 is amended as follows:

a. In the heading to the section and in paragraph (a), by removing the word ''countries'' and adding in its place the word ''regions''.

b. In paragraph (a), by removing the word ''country'' and adding in its place the word ''region''.

c. In paragraph (b), by removing the reference to ''§ 92.504(c) or § 92.501'' and adding in its place a reference to ''§ 93.504(c) or § 93.501''.

**§ 94.11 [Amended]**

121. Section 94.11 is amended as follows:

a. By removing the word ''countries'' each time it appears and adding in its place the word ''regions'' in the following places:

i. The heading to the section.
ii. Paragraph (a).
iii. Paragraph (b).
iv. Paragraph (c), introductory text.

b. In paragraph (a), by removing the words ''fresh, chilled, or frozen'' both times they appear and adding in their place the words ''fresh (chilled or frozen)''.

c. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (a).
ii. Paragraph (c), introductory text.
iii. Paragraph (c)(1).
iv. Paragraph (c)(2).
v. Paragraph (c)(3).

122. Section 94.12 is amended as follows:

a. By removing the word ''countries'' each time it appears and adding in its place the word ''regions'' in the following places:

i. The heading to the section.
ii. Paragraph (a).
iii. Paragraph (b)(1)(iv)(B)(*2*)(*ii*).

b. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (b), introductory text.
ii. Paragraph (b)(1)(ii)(A).
iii. Paragraph (b)(1)(iii)(A).
iv. Paragraph (b)(1)(iv), introductory text.
v. Paragraph (b)(1)(iv)(A).
vi. Paragraph (b)(1)(iv)(B)(*1*).
vii. Paragraph (b)(1)(iv)(B)(*2*)(*i*).
viii. Paragraph (b)(3).

c. By revising paragraph (b)(1)(iii)(B) to read as follows:

**§ 94.12 Pork and pork products from countries where swine vesicular disease exists.**

* * * * *

(b) * * *

(1) * * *

(iii) * * *

(B) Such pork or pork products shall be consigned directly from the port of entry in the United States to a meat processing establishment operating under Federal meat inspection and approved by the Administrator,[11] for heating to an internal temperature of 166 °F. During movement from the port of entry to the meat processing establishment, the pork or pork products must be moved under Department seals or seals of the the U.S. Customs Service, and shall be otherwise handled as the Administrator may direct in order to guard against the introduction and dissemination of swine vesicular disease. Seals applied under this section may not be broken except by persons authorized by the Administrator to do so; or

* * * * *

**§ 94.13 [Amended]**

123. Section 94.13 is amended as follows:

a. In the heading to the section and in the introductory text to the section, by removing the word ''countries'' each time it appears and adding in its place the word ''regions''.

b. In the introductory text to the section, by removing the words ''fresh, chilled, or frozen'' both times they appear and adding in their place the words ''fresh (chilled or frozen)''.

c. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. The introductory text to the section.

ii. Paragraph (b), introductory text.

iii. Paragraph (b)(1).

iv. Paragraph (b)(2).

**§ 94.14 [Amended]**

124. Section 94.14 is amended as follows:

a. In the heading to the section and in paragraph (a), by removing the word ''countries'' and adding in its place the word ''regions'.

b. In paragraph (a), by removing the word ''country'' and adding in its place the word ''region'.

c. In paragraph (b), by removing the reference to ''§ 92.501 or § 92.504(c)'' and adding in its place a reference to ''§ 93.501 or § 93.504(c)'.

125. In § 94.15, paragraph (c) is amended by removing the word ''countries'' both times it appears and adding in its place the word ''regions'', and a new paragraph (d) is added to read as follows:

**§ 94.15 Animal products and materials; movement and handling.**

* * * * *

(d) Any meat or other animal products not otherwise eligible for entry into the United States, as provided in this part and part 95 of this chapter, may transit the United States for immediate export if the following conditions are met:

(1) Notification of the transiting of such meat or other animal product is made by the importer to the Plant Protection and Quarantine officer at the United States port of arrival prior to such transiting;

(2) The meat or other animal product is contained in a sealed, leakproof carrier or container, which remains sealed while aboard the transporting carrier or other means of conveyance, or, if the container or carrier in which the meat or other animal product is transported is offloaded in the United States for reshipment, it remains sealed at all times;

(3) Such transit is limited to the maritime or airport port of arrival only, with no overland movement outside the airport terminal area or dock area of the maritime port; and

(4) The meat or other animal product is not held or stored for more than 72 hours at the maritime or airport port of arrival.

**§ 94.16 [Amended]**

126. Section 94.16 is amended as follows:

a. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (b), introductory text.

ii. Paragraph (c), introductory text.

iii. Paragraph (c)(1).

iv. Paragraph (c)(3).

v. Paragraph (d).

b. In paragraph (b)(2), first sentence, by removing the words ''for human food'.

c. In paragraph (c), introductory text, by removing the word ''countries'' and adding in its place the word ''regions'.

**§ 94.17 [Amended]**

127. Section 94.17 is amended as follows:

a. By removing the word ''countries'' each time it appears and adding in its place the word ''regions'' in the following places:

i. The heading to the section.

ii. Paragraph (o)(2)(ii)(A).

iii. Paragraph (o)(2)(ii)(B).

iv. Paragraph (o)(2)(iii)(A).

v. Paragraph (o)(2)(iii)(B).

b. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (a).

ii. Paragraph (b).

iii. Paragraph (d).

iv. Paragraph (i)(2)(vi).

v. Paragraph (i)(3)(vii).

vi. Paragraph (j)(1).

vii. Paragraph (j)(2).

viii. Paragraph (j)(3).

ix. Paragraph (k).

x. Paragraph (m)(1).

xi. Paragraph (o), introductory text.

xii. Paragraph (o)(2)(ii)(A).

xiii. Paragraph (o)(2)(ii)(B).

xiv. Paragraph (o)(2)(iii)(A).

xv. Paragraph (o)(2)(iii)(B).

**§ 94.18 [Amended]**

128. Section 94.18 is amended as follows:

a. In the heading to the section and in paragraph (a), by removing the word ''countries'' and adding in its place the word ''regions''.

b. In paragraph (b), introductory text, and paragraph (b)(1), by removing the words ''fresh, frozen, and chilled'' and adding in their place the words ''fresh (chilled or frozen)''.

c. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (b), introductory text.

ii. Paragraph (b)(2)(ii).

iii. Paragraph (b)(2)(iii).

iv. Paragraph (c), introductory text.

d. In paragraph (d), introductory text, by removing the words ''Fresh, chilled, or frozen'' and adding in their place the words ''Fresh (chilled or frozen)''.

**§ 94.19 [Amended]**

129. Section 94.19 is amended by removing the word ''country'' each time it appears and adding in its place the word ''region'' in both the heading and the text to the section.

**§ 94.20 [Amended]**

130. Section 94.20 is amended as follows:

a. In introductory text to the section, by removing the words ''fresh, chilled or frozen'' and adding in their place the words ''fresh (chilled or frozen)''.

b. In paragraph (a), by adding the word ''born,'' immediately before the word ''raised''.

c. In paragraph (b), by removing the word ''countries'' both times it appears and adding in its place the word ''regions''.

**§ 94.21 [Amended]**

131. Section 94.21 is amended as follows:

[11] The names and addresses of approved establishments may be obtained from, and request for approval of any establishment may be made to, the Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import-Export, 4700 River Road Unit 38, Riverdale, Maryland 20737–1231. Establishments will be approved only if the Administrator determines that the imported articles will be so handled at the establishment as to prevent the introduction and dissemination of livestock or poultry diseases into the United States. Approval of any establishment may be refused or withdrawn only after the operator thereof has been given notice of the proposed action and has had an opportunity to present his views thereon.

a. In the introductory text to the section, by removing the words ''fresh, chilled or frozen'' and adding in their place the words ''fresh (chilled or frozen)''.

b. In paragraph (c), by removing the word ''countries'' and adding in its place the word ''regions''.

## PART 95—SANITARY CONTROL OF ANIMAL BYPRODUCTS (EXCEPT CASINGS), AND HAY AND STRAW, OFFERED FOR ENTRY INTO THE UNITED STATES

132. The authority citation for part 95 continues to read as follows:

**Authority:** 21 U.S.C. 111, 136, and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(d).

133. Section 95.1 is amended by adding a definition of *Region*, in alphabetical order, to read as follows:

### § 95.1 Definitions.

* * * * *

*Region.* Any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

(1) A national entity (country);

(2) Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.)

(3) Parts of several national entities combined into an area; or

(4) A group of national entities (countries) combined into a single area.

* * * * *

### § 95.2 [Amended]

134. Section 95.2 is amended as follows:

a. In the heading to the section, by removing the word ''Country'' and adding in its place the word ''Region''.

b. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. The introductory text to the section.

ii. Paragraph (a).

ii. Paragraph (b).

### § 95.4 [Amended]

135. Section 95.4 is amended as follows:

a. In the heading to the section, by removing the word ''countries'' and adding in its place the word ''regions''.

b. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (a).

ii. Paragraph (b).

iii. Paragraph (c), introductory text.

### § 95.5 [Amended]

136. Section 95.5 is amended as follows:

a. In paragraph (a) and paragraph (c), by removing the word ''country'' each time it appears and adding in its place the word ''region''.

b. In paragraph (c), footnote 1, by removing the word ''countries'' and adding in its place the word ''regions''.

### § 95.7 [Amended]

137. In § 95.7, paragraph (a) and paragraph (c) are amended by removing the word ''country'' each time it appears and adding in its place the word ''region''.

### § 95.9 [Amended]

138. In § 95.9, paragraph (a) and paragraph (c) are amended by removing the word ''country'' each time it appears and adding in its place the word ''region''.

### § 95.11 [Amended]

139. In § 95.11, the introductory text of paragraph (b) and paragraph (b)(2) are amended by removing the word ''country'' each time it appears and adding in its place the word ''region''.

### § 95.14 [Amended]

140. In § 95.14, paragraph (a) is amended by removing the word ''country'' and adding in its place the word ''region';.

### § 95.15 [Amended]

141. Section 95.15 is amended by removing the word ''country'' and adding in its place the word ''region''.

### § 95.17 [Amended]

142. Section 95.17 is amended by removing the word ''country'' and adding in its place the word ''region''.

### § 95.21 [Amended]

143. Section 95.21 is amended by removing the word ''country'' and adding in its place the word ''region''.

### § 95.23 [Amended]

144. In § 95.23, the introductory text is amended by removing the word ''country'' both times it appears and adding in its place the word ''region''.

## PART 96—RESTRICTION OF IMPORTATIONS OF FOREIGN ANIMAL CASINGS OFFERED FOR ENTRY INTO THE UNITED STATES

145. The authority citation for part 96 continues to read as follows:

**Authority:** 21 U.S.C. 111, 136, 136a; 7 CFR 2.22, 2.80, and 371.2(d).

146. Section 96.1 is amended by adding a definition of *Region*, in alphabetical order, to read as follows:

### § 96.1 Definitions.

* * * * *

*Region.* Any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

(1) A national entity (country);

(2) Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.)

(3) Parts of several national entities combined into an area; or

(4) A group of national entities (countries) combined into a single area.

* * * * *

### § 96.2 [Amended]

147. Section 96.2 is amended as follows:

a. In the heading to the section, by removing the word ''countries'' and adding in its place the word ''regions''.

b. In paragraph (a), by removing the words ''country or part of a country'' and adding in their place the word ''region'' each time they appear.

c. In paragraph (b), by removing the word ''country'' and adding in its place the word ''region''.

### § 96.3 [Amended]

148. Section 96.3 is amended as follows: a. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (a).

ii. Paragraph (c), introductory text.

iii. Paragraph (c), ''FOREIGN OFFICIAL CERTIFICATE FOR ANIMAL CASINGS''.

b. In paragraph (c), ''FOREIGN OFFICIAL CERTIFICATE FOR ANIMAL CASINGS'', by removing the word ''Country'' and adding in its place the word ''Region''.

149. Section 96.10 is amended by revising the introductory text of paragraph (a) to read as follows:

### § 96.10 Uncertified casings; transportation for disinfection; original shipping containers; disposition of salt.

(a) Foreign animal casings imported into the United States without certification may be forwarded in customs custody to a USDA-approved facility for disinfection under APHIS supervision and release by the United States Customs authorities, provided that, before being transported over land in the United States, each and every container of such casings shall be disinfected by the application of a solution of sodium hydroxide prepared as follows:

* * * * *

150. Sections 96.15 and 96.16 are removed.

## PART 97—OVERTIME SERVICES RELATING TO IMPORTS AND EXPORTS

151. The authority citation for part 97 continues to read as follows:

**Authority:** 7 U.S.C. 2260; 49 U.S.C. 1741; 7 CFR 2.22, 2.80, and 371.2(d).

**§ 97.1 [Amended]**

152. In § 97.1, footnote 1 is amended by removing the reference to ''§§ 92.1 through 92.3'' and adding in its place a reference to ''§§ 93.102, 93.203, 93.303, 93.403, 93.503, 93.703, and 93.805''.

## PART 98—IMPORTATION OF CERTAIN ANIMAL EMBRYOS AND ANIMAL SEMEN

153. The authority citation for part 98 continues to read as follows:

**Authority:** 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 103–105, 111, 134a, 134b, 134c, 134d, 134f, 136, and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(d)

154. In part 98, the heading for subpart A is revised to read:

### Subpart A—Ruminant and Swine Embryos from Regions Free of Rinderpest and Foot-and-Mouth Disease; and Embryos of Horses and Asses

155. Section 98.2 is amended by revising the definitions of *Approved artificial insemination center and Approved embryo transfer unit,* and by adding a definition of *Region,* in alphabetical order, to read as follows:

**§ 98.2 Definitions.**

* * * * *

*Approved artificial insemination center.* A facility approved or licensed by the national government of the region in which the facility is located to collect and process semen under the general supervision of such government.

*Approved embryo transfer unit.* A facility approved or licensed by the national government of the region in which the facility is located for the artificial insemination of donor dams or for conception as a result of artificial breeding by a donor sire and for collecting and processing embryos for export under the general supervision of such government.

* * * * *

*Region.* Any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

(1) A national entity (country);

(2) Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.)

(3) Parts of several national entities combined into an area; or

(4) A group of national entities (countries) combined into a single area.

* * * * *

**§ 98.3 [Amended]**

156. Section 98.3 is amended as follows:

a. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. The introductory text to the section.

ii. Paragraph (a).

iii. Paragraph (i).

b. In paragraph (d), by removing the reference to ''part 92'' and adding in its place a reference to ''part 93''.

c. In paragraph (f), by removing the reference to ''§ 92.304(a)(2)'' and adding in its place a reference to ''§ 93.304(a)(2)'', by removing the reference to ''§ 92.404(a)(2)'' and adding in its place a reference to ''§ 93.404(a)(2)'', and by removing the reference to ''§ 92.504(a)(2)'' and adding in its place a reference to ''§ 93.504(a)(2).

**§ 98.4 [Amended]**

157. In § 98.4, paragraph (c)(1) and paragraph (c)(5) are amended by removing the word ''country'' each time it appears and adding in its place the word ''region''.

**§ 98.5 [Amended]**

158. In § 98.5, paragraph (a), the introductory text is amended by removing the word ''country'' each time it appears and adding in its place the word ''region''.

**§ 98.6 [Amended]**

159. Section 98.6 is amended by removing the reference to ''§ 92.303'' and adding in its place a reference to ''§ 93.303'', by removing the reference to ''§ 92.403'' and adding in its place a reference to ''§ 93.403'', and by removing the reference to ''§ 92.503'' and adding in its place a reference to ''§ 93.503''.

**§ 98.7 [Amended]**

160. In § 98.7, paragraph (g) is amended by removing the word ''country'' and adding in its place the word ''region''.

**§ 98.10a [Amended]**

161. Section 98.10a is amended as follows:

a. In the heading to the section, by removing the word ''countries'' and adding in its place the word ''regions''.

b. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (c).

ii. Paragraph (d).

iii. Paragraph (f), introductory text.

iv. Paragraph (f)(1).

v. Paragraph (f)(2)(i).

vi. Paragraph (f)(2)(ii).

162. The heading for subpart B is revised to read:

### Subpart B—Ruminant and Swine Embryos From Regions Where Rinderpest or Foot-and-Mouth Disease Exists

163. Section 98.11 is amended by removing the definition of *Country of origin* and by adding definitions of *Region* and *Region of origin,* in alphabetical order, to read as follows:

**§ 98.11 Definitions.**

* * * * *

*Region.* Any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

(1) A national entity (country);

(2) Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.);

(3) Parts of several national entities combined into an area; or

(4) A group of national entities (countries) combined into a single area.

*Region of origin.* The region in which the embryo is conceived and collected and from which the embryo is imported into the United States.

* * * * *

**§ 98.12 [Amended]**

164. Section 98.12 is amended as follows:

a. In paragraph (a), by removing the word ''countries'' and adding in its place the word ''regions''.

b. In paragraph (b), by removing the word ''country'' both time it appears and adding in its place the word ''region''.

**§ 98.13 [Amended]**

165. In § 98.13, paragraph (a) is amended by removing the word ''countries'' and adding in its place the word ''regions''.

**§ 98.14 [Amended]**

166. In § 98.14, paragraph (a) is amended by removing the word ''country'' each time it appears and adding in its place the word ''region''.

**§ 98.15 [Amended]**

167. Section § 98.15 is amended by removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

a. The introductory text to the section.

b. Paragraph (a)(5)(ii), introductory text.

c. Paragraph (a)(5)(iii).

d. Paragraph (a)(6).

e. Paragraph (b)(1).

f. Paragraph (b)(2).

g. Paragraph (b)(5).

**§ 98.16 [Amended]**

168. In § 98.16, the introductory text to the section is amended by removing the word ''country'' and adding in its place the word ''region''.

**§ 98.17 [Amended]**

169. Section 98.17 is amended by removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

a. Paragraph (f)(6)(i).
b. Paragraph (f)(6)(ii).
c. Paragraph (h)(2).

**§ 98.18 [Amended]**

170. In § 98.18, paragraph (c) is amended by removing the reference to ''§ 92.203(a)'' and adding in its place a reference to ''§ 93.203(a).

**§ 98.21 [Amended]**

171. In § 98.21, the heading is amended by removing the word ''countries'' and adding in its place the word ''regions''.

## Subpart C—Certain Animal Semen

172. Section 98.30 is amended by adding a definition of *Region,* in alphabetical order, to read as follows:

**§ 98. 30 Definitions.**

* * * * *

*Region.* Any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

(1) A national entity (country);

(2) Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.)

(3) Parts of several national entities combined into an area; or

(4) A group of national entities (countries) combined into a single area.

* * * * *

**§ 98.31 [Amended]**

173. In § 98.31, paragraph (b) is amended by removing the word ''country'' each time it appears and adding in its place the word ''region''.

**§ 98.32 [Amended]**

174. In § 98.32, paragraph (a) is amended by removing the word ''country'' and adding in its place the word ''region''.

**§ 98.34 [Amended]**

175. Section 98.34 is amended as follows:

a. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i. Paragraph (a)(1).
ii. Paragraph (a)(2).
iii. Paragraph (a)(3).
iv. Paragraph (b).
v. Paragraph (c), introductory text.
vi. Paragraph (c)(1)(i).
vii. Paragraph (c)(1)(ii).
viii. Paragraph (c)(3).
ix. Paragraph (c)(4).
x. Paragraph (c)(5).

b. In paragraph (a)(3) and in the heading to paragraph (c), by removing the word ''countries'' each time it appears and adding in its place the word ''regions''.

**§ 98. 35 [Amended]**

176. In § 98.35, paragraph (c) is amended by removing the word ''country'' each time it appears and adding in its place the word ''region''.

**§ 98.36 [Amended]**

177. In § 98.36, paragraph (a)(1) and paragraph (a)(2) are amended by removing the word ''country'' each time it appears and adding in its place the word ''region''.

**§ 98.37 [Amended]**

178. Section 98.37 is amended as follows:

a. In the heading to the section, by removing the word ''countries'' and adding in its place the word ''regions''.

b. By removing the word ''country'' each time it appears and adding in its place the word ''region'' in the following places:

i Paragraph (c).
ii. Paragraph (d).
iii. Paragraph (f), introductory text.
iv. Paragraph (f)(1).
v. Paragraph (f)(2)(i).
vi. Paragraph (f)(2)(ii).

## PART 130—USER FEES

179. The authority citation for part 130 continues to read as follows:

**Authority:** 5 U.S.C. 5542; 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 102–105, 111, 114, 114a, 134a, 134b, 134c, 134d, 134f, 135, 136, and 136a; 7 CFR 2.22, 2.80, and 371.2(d).

**§ 130.1 [Amended]**

180. Section 130.1 is amended by removing the reference to ''part 92'' and adding in its place a reference to ''part 93'' in the following places:

a. The definition of *Feeder animal.*

b. The definition of *Privately operated permanent import-quarantine facility.*

c. The definition of *Zoo animal,* footnote 2.

**§ 130.2 [Amended]**

181. Section 130.2 is amended by removing the references to ''part 92'' and adding in their place references to ''part 93'' in the following places:

a. Paragraph (a), footnote 5.

b. Paragraph (a), in the table, under the heading ''Animal or bird'', in the first entry under ''Birds''.

c. Paragraph (e).

**§ 130.3 [Amended]**

182. In § 130.3, paragraph (a)(3) is amended by removing the references to ''92.103, 92.204, 92.304, 92.404, or 92.504'' and adding in their place references to ''93.103, 93.204, 93.304, 93.404, or 93.504''.

**§ 130.10 [Amended]**

183. In § 130.10, paragraph (a), footnote 7 is amended by removing the reference ''part 92'' and adding in its place a reference to ''part 93''.

Done in Washington, DC, this 22nd day of October, 1997.

**Terry L. Medley,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 97–28473 Filed 10–23–97; 12:52 pm]

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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

**[Docket No. 94–106–8]**

**RIN 0579–AA71**

### APHIS Policy Regarding Importation of Animals and Animal Products

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice.

**SUMMARY:** The Animal and Plant Health Inspection Service is adopting a policy that recognizes regions, and levels of risk among those regions, with regard to the importation of animals and animal products. We are applying this policy to all species of animals regulated under the Code of Federal Regulations, title 9, chapter I, subchapter D, including, but not limited to, ruminants, swine, birds, poultry, and horses. We consider this policy to be consistent with and to meet the requirements of international trade agreements entered into by the United States.

**ADDRESSES:** You may submit comments on this statement of policy by sending an original and three copies of your comments to Docket No. 94–106–8, 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. 94–106–8. 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 reading room.

**FOR FURTHER INFORMATION CONTACT:** Dr. Gary Colgrove, Chief Staff Veterinarian, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20237–1231, (301) 734–8590.

**SUPPLEMENTARY INFORMATION:**

#### Purpose

In this document, the Animal and Plant Health Inspection Service (APHIS) sets forth our policy regarding the manner in which we will apply the concepts of regionalization and risk analysis to regulating the importation of animals and animal products into the United States. We are applying this policy to all species of animals regulated under the Code of Federal Regulations, title 9 (9 CFR), chapter I, subchapter D, including, but not limited to, ruminants, swine, birds, poultry, and equines.

We have traditionally viewed animal disease distribution on a country-by-country basis, with the presence or absence of a particular disease anywhere within a country's borders serving to establish, for regulatory purposes, the status of the entire country with regard to that disease. That approach has had the effect of establishing an all-or-nothing standard of risk avoidance that precludes our consideration of factors such as disease-free zones or low disease prevalence within a country when establishing restrictions on the importation into the United States of animals and animal products. Consistent with our obligations under international trade agreements, APHIS is altering its traditional country-based import restrictions by recognizing that there are identifiable and measurable gradations in the degree of disease risk presented by imported animals and animal products, and that these gradations are often tied more to climatological, geographical, and biological factors than to national political boundaries.

To help ensure that our standards for regulating imports on a regional basis and for assessing disease risk within defined regions are transparent and applied on a consistent basis, we have decided to issue this policy statement setting forth the factors we will take into account when considering future requests to export animals or animal products to the United States from distinct or definable regions that may not be national entities.

#### The Concept of Regionalization

Regionalization (division of areas into regions) is rooted in the concept that restrictions on the movement of animals and animal products for the purpose of disease control are biologically and ecologically most logical when applied to areas that are geographically homogenous with respect to disease distribution and livestock health infrastructures. Under this concept of regionalization, regions may be countries, parts of countries, or groups of countries.

Regionalization is used for:

- Localization and containment of existing, exotic, or newly emerging diseases.
- Recognition of distinct, definable areas of reduced risk within areas of greater risk.
- Providing a geographic basis for sanitary (animal) measures to reduce the risk of disease introduction through the movement of animals and animal products.

Contemporary international regionalization expectations are outlined in the World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) Agreement that was authorized by the General Agreement on Tariffs and Trade (GATT). The WTO-SPS Agreement obliges member countries to develop transparent SPS measures based on sound scientific principles, risk assessment, and relevant international standards, and to apply them without discrimination, using the principles of equivalence and regionalization.

The United States has applied these concepts for decades in domestic programs for controlling brucellosis, tuberculosis, and pseudorabies, and for containing and eradicating outbreaks of exotic diseases such as highly pathogenic avian influenza. These concepts have also been used to facilitate exports by regionalizing the United States for bluetongue and other agents.

#### Recent APHIS Rulemaking

We have already applied the concept of regionalization of a region of low risk to the importation of beef from Argentina. On June 26, 1997, we published a final rule in the **Federal Register** (62 FR 34385–34394, Docket No. 94–106–5) allowing the importation of fresh, chilled or frozen beef from Argentina under certain import conditions, based on our determination that the unrestricted importation of such beef would present a low risk of introducing FMD into the United States. We have also applied the concept of regionalization in several other recent rulemaking actions. For example, on May 9, 1997, we published in the **Federal Register** a final rule (62 FR 25439–25443, Docket No. 94–106–6) to allow, under certain conditions, the importation of fresh, chilled or frozen pork from the State of Sonora, Mexico. On June 12, 1997, we published in the **Federal Register** a proposal (62 FR 32051–32053, Docket No. 97–002–1) to recognize all of Italy, except Sardinia, as an area in which African swine fever does not exist. Each of these actions was taken after we thoroughly investigated, through site visits and other data collection, the disease history, surveillance systems, animal health policies, and infrastructure of the areas in question. This document gives notice of our intent to apply such approaches to regionalization and risk analysis in future rulemaking actions.

#### Regionalization and Risk Assessment

The principles of the WTO–SPS Agreement are consistent with the

regulatory strategies adopted by many national veterinary services, as they have adapted to advances in animal health technology, progress in the control and eradication of major animal plagues, worldwide privatization of regulatory responsibilities, changing national boundaries, formation of trading blocks, and movement toward more transparent governmental decisionmaking.

In response to these changes, APHIS is adopting a policy of evaluating hazards presented by proposed animal and animal product importations based on the disease risk associated with the region from which they are exported, rather than on ''disease-free'' or ''not-disease-free'' statuses determined on a country-by-country basis. APHIS will analyze the disease risk involved and fashion appropriate import requirements over a wide range of variables. Thus, this policy approach will encompass the concepts of regionalization and risk assessment.

Risk assessment consists of identifying risk factors and evaluating their seriousness. The concept of assessing risk has underpinned regulatory decision-making in numerous sectors for some time. There are many risk assessment techniques. Some are very simple and others are extremely complex. APHIS has developed guidelines it has used and will use in the future in assessing the risk of disease introduction from the unrestricted importation of animals and animal products from specified regions, and in determining which conditions of importation will reduce any disease risk to a negligible level. These guidelines are discussed below.

**Definition of ''Region''**

With only minor exceptions, the regulations in 9 CFR, chapter I, subchapter D, are currently based on the disease status of entire countries. This document gives notice of APHIS's policy to consider, for purposes of the importation of animals and animal products, the disease status of regions. APHIS considers a region to be any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

- A national entity (country);
- Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.);
- Parts of several national entities combined into an area; or
- A group of national entities (countries) combined into a single area.

It is important to note that a region can be a national entity. Consistent with this concept, we are continuing to apply on a country-by-country basis the importation requirements currently set forth in 9 CFR, chapter I, subchapter D, for countries listed as being affected or not affected with specific diseases. We will continue to apply the current importation requirements to these countries until we receive a request to ''regionalize'' a country into regions, or to ''regionalize'' a group of countries into a region, or both. Once a request is made, we will evaluate the request and its supporting documentation to determine if the requested action is scientifically supportable, and solicit public comment on the request and its supporting data.

**New Paradigms to Describe Risk**

In reality, ''free'' is not the same as ''risk-free,'' and a ''not-free'' designation does not ensure that all regions so considered pose an identical risk. Under the current regulations in 9 CFR, chapter I, subchapter D, unrestricted imports (i.e., importations subject to no import conditions) from countries classified as ''free'' of a certain disease can present different levels of risk. Current §§ 94.11 and 94.13 address this risk by imposing restrictions on the importation of meat from countries that are ''free'' of certain diseases, but that present a higher disease risk due to importation practices of these countries or the geographical proximity to countries with a higher disease risk. We consider the countries listed in §§ 94.11 and 94.13 to be ''modified-free'' countries.

Levels of risk exist upon a continuum. The extremes of this continuum can be exemplified by the risk statuses of countries set forth in the current regulations. For instance, § 94.1 of the current regulations lists countries considered to be free of rinderpest and foot-and-mouth disease (FMD). The two diseases are considered to exist in all countries not included on the ''free'' list. Under APHIS policy, conditions for ''freedom'' from disease under the current regulations include the requirement that vaccination for the disease not be carried out in the country in question. Thus, certain countries might not be included on the ''free'' list, even though they have reported no case of the disease for several years, because they continue to vaccinate for the disease. At the other end of the spectrum are countries where rinderpest or FMD is known to exist. Under the current regulations, all countries listed as those in which the diseases are considered to exist are treated as if the diseases exist throughout those countries at a uniformly high prevalence.

The import conditions applied under the current regulations for animals and their products reflect the extremes of ''free'' as currently understood and ''not free.'' On the one hand, countries considered free of FMD and rinderpest may in most cases export animals to the United States with only a certificate of the animal's origin and health (subject to general inspection and quarantine at the U.S. port of arrival). At the other extreme, animals from countries where the diseases are considered to exist may not be imported into the United States, unless they have undergone pre-embarkation quarantine and testing in the country of origin and are imported through the high-security Harry S Truman Animal Import Center.

As noted above, until otherwise requested by foreign regions and approved by APHIS, we will continue to operate under the system of ''free,'' ''not-free,'' and ''modified-free'' on a country-by-country basis for those countries currently so listed in 9 CFR, chapter I, subchapter D. However, we will, in the future, evaluate the risk of importations and seek to determine the degree of risk involved to ascertain where the proposed importation would fall on the risk continuum. This will allow APHIS to address the degree of risk involved in a particular type of importation, rather than trying to fit it into one of the three categories contained in the current regulations.

**Factors Considered in Assessing Risk**

Factors affecting the risk levels of ''free'' regions are many and can include geographical proximity to areas where the disease exists, and importation practices that increase the risk that the disease might be introduced into the ''free'' region. Similarly, significant differences in risk can exist among regions in which a particular disease is known to exist, depending on the prevalence of the disease (the number of cases at a given time) or the infrastructure in place for identifying, containing or eradicating the disease.

In this policy statement, we are setting forth the factors we will consider in determining the risk of unrestricted importations from a region. Broadly, these factors are the following:

- The authority, organization, and infrastructure of the veterinary services organization in the region.
- The type and extent of disease surveillance in the region—e.g., is it passive and/or active; what is the quantity and quality of sampling and testing?
- Diagnostic laboratory capabilities.

• Disease status—is the disease agent known to exist in the region? If ''yes,'' at what prevalence? If ''no,'' when was the most recent diagnosis?

• The extent of an active disease control program, if any, if the agent is known to exist in the region.

• The vaccination status of the region. When was the last vaccination? What is the extent of vaccination if it is currently used, and what vaccine is being used?

• Disease status of adjacent regions.

• The degree to which the region is separated from regions of higher risk through physical or other barriers.

• The extent to which movement of animals and animal products is controlled from regions of higher risk, and the level of biosecurity regarding such movements.

• Livestock demographics and marketing practices in the region.

• Policies and infrastructure for animal disease control in the region—i.e., emergency response capacity.

**Characterization of Levels of Risk**

In practice, regions could have numerous possible combinations of the above factors. For instance, one region might have a low prevalence of a disease (the number of cases at a given time), but have loosely restricted borders with adjacent regions where the disease is present. Another region might have tighter border controls but a higher incidence of the disease (the number of new cases over a given period of time). Two regions with identical histories of disease incidence and disease prevalence might differ in that vaccination continues in one region, but not in the other. Two regions might theoretically share all risk characteristics, including adjacency to a region where a disease of concern is known to exist. However, in one case, the disease in the affected neighboring region might exist close to the border. In the other, it might exist two time zones away, if the neighbor is a large country that has not yet requested to be subdivided into regions. This one variable could affect the actual risk level between the two regions, and could potentially support two different sets of conditions necessary to reduce the risk of the importation of animals and animal products to a negligible level. Therefore, although each of the factors we will consider are accepted on an international level as potentially affecting the disease risk in a region, the weight each of the factors will be given will depend on the individual circumstances of the region.

Because of the number of potential variables and the vast number of possible combinations of those variables in assessing the risk of unrestricted importation of animals and animal products from a region, the precise combination of measures necessary to reduce the risk of disease introduction to a negligible level may vary from region to region depending on the commodities to be imported and the diseases of concern.

Recognizing these potential variables, we nonetheless consider it useful to provide benchmarks or ''targets'' of general risk characterization, by dividing the continuum of risk into five general categories, based on the risk factors described above. These benchmark risk categories are:

• Negligible risk;
• Slight risk;
• Low risk;
• Moderate risk;
• High risk.

In order to determine the risk category of a region, we must have or be supplied with sufficient information to evaluate the region's level of risk. Any region for which sufficient data is not available to make such an evaluation would be considered to be high risk until information became available to support an alternative determination.

As noted above, there are factors that we always look at in determining the level of risk that unrestricted importations from a region would present (veterinary infrastructure, disease status, disease status of adjacent regions, vaccination status, etc.). We have weighed these factors in our determination of a country's disease status under the current regulations, and will continue to do so in the future. The difference between the current regulations and the policy we are adopting is that, in the future, our consideration of these factors will not always result in one of the three current classifications of ''free'' ''not free,'' or ''modified free.'' In theory, and likely in practice, regions where an animal disease is not known to exist may present different levels of risk, and regions where an animal disease is known to exist may likewise present different levels of risk. We will establish import conditions appropriate to each of the regions in a transparent, scientific manner, subject to public review and comment, as discussed below. A region will be able, however, to determine how we will generally view its animal disease risk, according to the following factors and scenarios.

1. *Negligible Risk.* A region in which all of the following factors are present would generally be considered a region of *negligible risk* for a restricted disease agent:

• The restricted agent has not been diagnosed within the region for a period of time appropriate for that agent. This period of time will depend on the disease in question, but can range from 1 year for a disease such as FMD, to a longer period of time for diseases with long incubation times, such as spongiform encephalopathies and mycobacterial diseases.

• The restricted agent is not known to exist within any adjacent defined region.

• Vaccination for the restricted agent has been prohibited within the region for a period of time appropriate to the disease in question (exceptions may be made for certain diseases such as vector-transmitted diseases, or for animals specifically vaccinated to meet import requirements of other regions, and such vaccination would not increase the risk of importing the restricted agent into the United States).

• Any adjacent regions of slight risk or low risk for the restricted agent are separated by natural or man-made physical barriers or protected borders, or other movement controls and other measures and restrictions that are equivalent to those imposed in the United States for similar diseases subject to domestic control programs.

• All border access points from adjacent regions of slight risk or low risk for the restricted agent are controlled to prevent movement of susceptible animals or animal products from the adjacent regions except under conditions that achieve the same level of biosecurity as required for importations from such regions of greater risk into the United States.

• Movement of animals and animal products into the region from regions of greater than negligible risk for the restricted agent is done only under conditions that achieve the same level of biosecurity as required for importations from such regions of greater risk into the United States.

• The region maintains an adequate passive surveillance system with the demonstrated capability of detecting restricted agents in a timely fashion.

• The region maintains policies and infrastructure to respond to any occurrences of a restricted agent.

2. *Slight Risk.* In general, a particular disease agent would not be known to exist in a region of slight risk, but adjacency to or extensive trade with regions of higher risk levels would create a greater risk of disease exposure than exists in a region of negligible risk. A region in which all of the following factors are present would be considered a region of *slight risk* for a restricted disease agent:

• The restricted agent has not been known to exist in the region for a period of time appropriate for that agent.

• Vaccination for the restricted agent is prohibited within the region (exceptions may be made for certain restricted agents such as vector-transmitted diseases, or for animals specifically vaccinated to meet import requirements of other regions, and such vaccination would not increase the risk of importing restricted agents into the United States).

• Any animals previously vaccinated against the disease have been slaughtered or moved out of the region, or are under provisional quarantine (exceptions may be made for certain restricted agents such as vector-transmitted diseases, or for animals specifically vaccinated to meet import requirements of other regions, and such vaccination would not increase the risk of importing restricted agents into the United States).

• Any adjacent regions of greater than slight risk for the restricted agent are separated by natural or man-made physical barriers or protected borders, or other movement controls and other measures that are equivalent to those employed in the United States for similar diseases subject to domestic control programs.

• All border access points from regions of greater than slight risk for the restricted agent are strictly controlled to prevent movement of susceptible animals or animal products from the adjacent regions, except under conditions that achieve the same level of biosecurity as required for importations from such regions of greater risk into the United States.

• Movement of animals and animal products into the region from regions of greater than slight risk for the restricted agent is done only under conditions that achieve the same level of biosecurity as required for importation from such regions of greater risk into the United States.

• The region maintains adequate passive and/or active surveillance systems with the demonstrated capability of detecting restricted agents in a timely fashion.

• The region maintains policies and infrastructure to respond to any occurrences of a restricted agent.

3. *Low Risk*. A particular disease agent would not be known to exist in a region of low risk, but continued vaccination would create concerns about residual infection and/or masking of the agent. A region in which all of the following factors are present would be considered a region of *low risk* for a restricted disease agent.

• The restricted agent has not been diagnosed within the region during the past year, except for diseases with long incubation periods such as spongiform encephalopathies and mycobacterial diseases, and the prevalence of the restricted agent has been low over a period of time appropriate to the disease in question.

• Vaccination for the restricted agent is prohibited within the region or is limited to those herds that are at greatest risk of exposure from animals from regions of higher risk levels (exceptions may be made for certain diseases such as vector-transmitted diseases, or for animals specifically vaccinated to meet import requirements of other regions, and such vaccination would not increase the risk of importing restricted agents into the United States).

• Any adjacent regions of greater risk for the restricted agent are separated by natural or man-made physical barriers, or protected borders, or other movement controls and other measures that are equivalent to those employed in the United States for similar diseases subject to domestic control programs.

• All border access points from adjacent regions of greater risk for the restricted agent are controlled to prevent movement of susceptible animals or animal products from the adjacent regions except under conditions that achieve the same level of biosecurity as required for importations from such regions of greater risk into the United States.

• Movement of animals and animal products into the region from regions of greater risk for the restricted agent is done only under conditions that achieve the same level of biosecurity as required for importation from regions of greater risk into the United States.

• The region maintains adequate passive and active surveillance systems with the demonstrated capability of detecting restricted agents in a timely fashion.

• The region maintains policies and infrastructure to respond to any occurrences of the restricted agent.

4. *Moderate Risk*. A particular disease agent would be known to exist in a region of moderate risk, but at a low level. A region in which all of the following factors are present would be considered a region of *moderate risk* for a restricted disease agent.

• The restricted agent has been diagnosed within the region during the past year, or within a longer period of time for diseases with long incubation periods such as spongiform encephalopathies and mycobacterial disease, but the prevalence of the restricted agent has been low for a period of time appropriate for the disease agent.

• An active control program with a goal of eradication for the restricted agent is in operation in the region.

• Vaccination for the restricted agent is currently limited to those herds at greatest risk of infection (exceptions may be made for certain diseases, such as vector-transmitted diseases, or for animals specifically vaccinated to meet import requirements of other regions, and such vaccination would not increase the risk of importing restricted agents into the United States).

• Any adjacent regions of greater risk are separated by natural or man-made physical barriers or protected borders, or other movement controls and measures equivalent to those employed in the United States for similar diseases subject to domestic control programs.

• All border access points from adjacent regions of greater risk for the restricted agent are strictly controlled to prevent movement of susceptible animals or animal products from the adjacent regions except under conditions that achieve the same level of biosecurity as required for importation from such regions of greater risk into the United States.

• Movement of animals and animal products into the region from regions of greater risk is done only under conditions that achieve the same level of biosecurity as required for importation from regions of greater risk into the United States.

• The region maintains adequate passive and active surveillance systems with the demonstrated capability of detecting restricted agents in a timely fashion.

• The region maintains policies and infrastructure to eliminate any outbreaks of the restricted agent that may occur.

5. *High Risk*. A disease agent would be known to exist in a region of high risk, possibly at a high level. A region in which the following factors are present would be considered a region of *high risk* for a restricted disease agent.

• The restricted agent has been diagnosed within the region within the past year, or within a longer period of time for diseases with long incubation periods such as spongiform encephalopathies and mycobacterial disease, and the prevalence of the disease agent in the time period appropriate to the disease agent exceeds that of a moderate-risk region.

• A control program for restricted agents may be in operation in the region but does not meet the minimum standards for a region of moderate risk.

• Vaccination for the restricted agent may vary from herd to herd.

• Movement of animals and animal products into the region may not be adequately controlled from regions of moderate risk or high risk for the restricted agent.

• The region does not maintain a passive and active surveillance system for the restricted agent at a level that meets standards for a region of moderate risk.

• The region may or may not maintain policies and infrastructure to effectively control and restrict spread of any outbreaks of the restricted agent that may occur.

It should be noted that of the five general categories of risk set forth above, the categories referred to as ''negligible risk,'' ''slight risk,'' and ''high risk'' correspond to risk classifications as set forth in the current regulations. ''Negligible risk'' is comparable to our current free-without-restrictions status. ''Slight risk'' is comparable to our current modified-free status, applied to those countries where a disease is not known to exist but which, because of their proximity to countries where the disease exists or because of their importation practices, are considered to present more than a negligible risk of unrestricted importation of meat products. ''High risk'' is comparable to those countries where a disease is known to exist. To these three current classifications, the factors described above add the categories of ''low risk'' (to address regions that have reported no cases of disease over a specified period of time but that still vaccinate for the disease) and ''moderate risk'' (to address those regions where a disease may exist on a limited basis, but where it is adequately controlled and contained). Examples of regions that would fall under one of these two additional characterizations, along with an example of a high risk region, are as follows.

*Example 1: A Region Considered To Present a Low Risk of FMD Introduction Through Unrestricted Importation*

The example of a region characterized as presenting a low risk for FMD is one that we recently applied with regard to the importation of beef from Argentina. Because the last outbreak of FMD occurred in Argentina in 1994, we considered the disease risk in Argentina to be low, although higher than in other countries in which the disease has not occurred, due to the following factors:

(1) Vaccinations for FMD still continue in Argentina;

(2) Argentina supplements its national meat supply by importing fresh, chilled and frozen meat of ruminants and swine from countries where some prevalence of FMD occurs; and

(3) Argentina shares land borders with Brazil and Bolivia, for which we do not have enough information to establish a disease risk characterization for FMD.

For these reasons, we established import conditions on the importation of beef from Argentina that do not apply to other countries in which FMD is not known to occur. These conditions are discussed below under the heading ''Examples of Import Conditions.''

*Example 2: A Region Considered to Present a Moderate Risk of FMD Introduction Through Unrestricted Importation*

In this example, Region X has had an outbreak of FMD in the past year, but the prevalence of the disease in recent years has been low. Region X borders a region where FMD is known to exist. However, Region X has in place adequate passive and active surveillance systems for detection and reporting of the disease. Further, Region X has in place an active control program with the goal of eradication of FMD. Vaccination for FMD is currently limited to those herds at greatest risk of infection. Region X maintains policies and infrastructure to *eliminate* any outbreaks of the restricted agent that may occur.

Compare Region X to Region Y, which is:

*Example 3: A Region Considered To Present a High Risk of FMD Introduction Through Unrestricted Importation*

Region Y is identical to Region X in every way except two. First, it does not have an active control program with the goal of eradication of FMD. Second, it has in place policies only to *restrict,* rather than *eliminate,* outbreaks of FMD.

We would consider Region X to present a moderate risk of the introduction of FMD through unrestricted importation. We would consider Region Y to present a high risk.

**Import Conditions Based on Risk**

The risk characterizations described above are guidelines for the use of regions seeking to export animals or their products to the United States, and to provide guidance as to the factors we consider in deciding where a particular region falls on the disease risk continuum. The risk characterizations themselves do not determine whether an animal or its products may be safely imported into the United States, nor do they dictate the precise import conditions that would be appropriate to the importation of a particular commodity. But they do provide an indication as to the severity of the disease risk and the necessary restrictions that we would apply to importations to reduce the disease risk to a negligible level.

The actual decision whether to allow importations, and under what conditions, would be based on the outcome of a risk analysis conducted on a particular commodity from a particular region. In accordance with the WTO–SPS Agreement, we recognize that different import conditions might achieve equivalent results in reducing disease risk. However, the final determination of which import conditions to impose, and whether different sets of conditions are equivalent, will rest with APHIS. The WTO–SPS Agreement principles require that SPS measures be equitably applied, scientifically sound, guided by international standards, and ''transparent.'' Signatory countries must also recognize that equal levels of risk mitigation can be achieved by applying differing sanitary measures (equivalence), based on risk-assessments applied on a regional basis.

In accordance with the WTO–SPS Agreement principles, it will be our policy to establish appropriate conditions for the importation of animals and animal products based either on international standards or as the result of an individual assessment of risk of the importation of a particular type of commodity from a particular region. A document describing the Agency's internal guidelines for risk assessment is currently under development. It will be made available electronically upon completion. In general, we will process applications for regionalization according to the following procedure:

The potential exporting region must submit a request to the APHIS Administrator for approval to export a particular type of animal or animal product to the United States. Along with the request, the region must provide information addressing the areas described above in this notice, under the heading ''Factors Considered in Assessing Risk.'' This information will be made available to the public prior to our initiating any rulemaking action on the request. Additional information may be requested from the exporting region depending upon the specific commodity and the risk being evaluated.

Once we have received from a potential exporting region the information necessary to conduct a risk assessment, and have evaluated the risk, we will make a determination whether an import can be safely allowed and

under what conditions. If we believe the importation can be safely allowed, we will propose in the **Federal Register** to allow such importations, and under what conditions, along with a discussion of how we reached that decision. We will then provide a period of time during which the public may comment on our proposal. We will find most useful those comments that support their position with verifiable data or scientific information. During the comment period, the public will have access, both in hard copy and electronically, to the information upon which we based our risk analysis, as well as to our methodology in conducting the analysis. Once we have reviewed all comments received, we will make a final decision on what conditions will be necessary to allow the importation in question, and will publish that decision in the **Federal Register**.

Although the import conditions applied in each situation may vary according to the region, the disease, and the commodity involved, we anticipate, based on our experience enforcing the current regulations, that similar levels of risk will require similar conditions of importation. We have adopted, and have been applying for decades, a body of risk mitigation measures that will likely be used in some combination for each importation. These can include measures ranging from something as simple as a certificate of origin, to the requirement that animals intended for importation from regions of high risk be quarantined at APHIS's high-security Harry S Truman Animal Import Center, to outright prohibition of an importation.

The broad risk management options available for application, either individually or in combination, to animals or their products are:

- Certificate of origin of animals and animal products.
- Tests and inspection of imported animals or products.
- Tests and inspections of herds or premises of origin.
- Treatment of animals or products.
- Quarantine of imported animals.
- Restricted use or movement of imported animals or products.

Not all of the options are appropriate for every disease agent, so different strategies will be necessary for different agents. Some of the variabilities of the disease agents include:

- The incubation period.
- The duration of carrier status in animals.
- The number of potential host species that may be affected.
- The survivability of the disease agent outside the host animal.
- The effectiveness of available test procedures to detect the disease agent.
- The effectiveness of available treatment procedures to eliminate the disease agent or its vector.
- The availability of technology to eradicate the disease agent if it were introduced.
- If the disease agent were introduced, the potential costs (both economic and environmental) to eradicate it, or potential costs into perpetuity if the agent cannot be eradicated.

**Application of Import Conditions**

The three examples we presented earlier in this document of regions characterized as either ''low risk,'' ''moderate risk,'' or ''high risk'' for FMD can also be used to illustrate the types of mitigation measures we would consider appropriate for a disease such as FMD, which is a serious disease with significant potential costs in the event of introduction and establishment. Examples of the types of import conditions that would be appropriate are set out as follows. Please note, however, that the precise import conditions in any specific case will depend on all of the factors affecting a particular region.

*Example 1: Importation of Beef From a Region Characterized as Low-Risk for FMD*

As noted above, we recently made final a rule allowing the importation of beef from Argentina, which we determined to be a country that would present a low risk of FMD introduction if unrestricted imports were allowed into the United States. Because of the potentially severe consequences of FMD introduction, we considered it necessary to apply the following import conditions to any fresh, chilled or frozen beef imported from Argentina, and to cured or cooked beef from Argentina that does not meet the requirements of 9 CFR 94.4. An authorized official of Argentina must certify on a meat inspection certificate that each of the following conditions was met.

(1) The meat is beef that originated in Argentina;

(2) The beef came from bovines that were moved directly from the premises of origin to the slaughterhouse without any contact with other animals;

(3) The beef has not been in contact with beef from regions in which FMD is considered to exist;

(4) The beef came from bovines that originated from premises where FMD and rinderpest have not been present during the lifetime of any of the bovines slaughtered for export of beef;

(5) The beef is from bovines that originated from premises on which ruminants or swine have not been vaccinated with modified or attenuated live viruses for FMD at any time during the lifetime of any of the bovines slaughtered for export of beef;

(6) The beef originated from premises where no bovines have been vaccinated for rinderpest at any time during the lifetime of any of the bovines slaughtered for export of beef;

(7) All bone, blood clots, and lymphoid tissue have been removed from the beef; and

(8) The beef comes from carcasses that have been allowed to maturate at 40 to 50 °F (4 to 10 °C) for a minimum of 36 hours after slaughter, and have reached a pH of 5.8 or less in the loin muscle at the end of the maturation period. Any carcass in which the pH does not reach 5.8 or less may be allowed to maturate an additional 24 hours and be retested, and, if the carcass still does not reach a pH of 5.8 or less after 60 hours, the beef from the carcass may not be imported into the United States.

*Example 2. Importation of Beef From a Region Characterized as Moderate Risk for FMD*

In the examples or risk characterization we provided earlier in this document, we considered Region X to be a region of moderate risk for FMD. Although the actual conditions for the importation of beef from Region X might be established by means of a risk analysis, based on our experience enforcing the regulations, it is likely that the conditions would be similar to those for a low risk region, with the following differences due to the existence of FMD in the region and the resulting higher risk:

1. The beef would have to come from bovines that originated from premises where FMD or rinderpest has not been diagnosed within 15 statute miles (25 kilometers) within the previous 12 months; and

2. The beef would have to be held at no more than 40 °F (4 °C) for a minimum of 14 days before export, during which time the premises of origin of all animals from which the beef in the shipment came would have to remain free of FMD and rinderpest.

*Example 3: Importation of Beef From a Region Characterized as High Risk for FMD.*

The importation of fresh, chilled or frozen beef would be prohibited from a

region characterized as presenting a high risk for FMD.

**Diseases of Concern**

The current regulations specifically address a number of diseases subject to import regulations, either because they are not known to exist in the United States or because they are subject to Federal or cooperative Federal/State control or eradication programs in the United States. We will continue to regulate the importation of animals and their products with regard to these diseases. Additionally, it will be our policy to consider the risk presented by certain diseases not currently specifically listed in 9 CFR when determining whether to allow an importation and under what conditions.

With regard to ruminants and swine, the diseases we are specifically naming here have, in many cases, been of concern even under the current regulations, but have not posed a significant practical risk because the countries in which they exist have also been countries in which rinderpest or FMD exists. Accordingly, such importations were prohibited. The current regulations ban the importation into the United States of most animals and animal products from countries in which rinderpest or FMD exists. In those cases where animals or animal products are allowed to be imported from these countries, they must meet stringent quarantine or processing requirements. These prohibitions and safeguards effectively ban many animals and products affected with other diseases.

However, several factors now make it necessary to consider specific regulatory restrictions for certain diseases not currently addressed in the regulations. The first factor is the policy we are adopting of providing for regionalization and for various levels of characterization of disease risk. For example, unlike under the current regulations, the fact that FMD exists in one region of a country may not significantly restrict the importation of animals and animal products from another region of the same country, if the two regions are so separated and monitored that the risk of the disease being transferred from one region to the other is negligible. This is a departure from the current regulations, in which FMD in any part of a country determines the FMD status of the entire country.

The second factor is the progress many countries have made in eradicating, or moving toward eradication of, rinderpest and FMD in specific regions. In countries where FMD exists, an increasing number of regions have eradicated or come close to eradicating the disease. Therefore, under our policy of regionalization, import restrictions due to FMD in one part of a country can no longer be relied upon to guard against the importation of other animal diseases of concern.

In addition to FMD and rinderpest, other disease agents that are specifically addressed in current 9 CFR parts 92 and 94 are: In part 94, African swine fever virus, hog cholera (also known as classical swine fever virus), swine vesicular disease virus, exotic Newcastle disease (END) virus (also known as velogenic Newcastle disease or VVND virus), fowl pest (also known as fowl plague or highly pathogenic avian influenza), bovine spongiform encephalopathy, and salmonella enteritidis phage type 4; in part 92, contagious pleuropneumonia, scrapie, surra caused by *Trypanosoma evansi*, fever ticks and other ticks, vesicular stomatitis, dourine caused by *Trypanosoma equigenitalium*, glanders caused by *Pseudomonas mallei*, equine piroplasmosis caused by *Babesia equi* or *B. caballi*, equine infectious anemia, contagious equine metritis caused by *Taylorella equigenitalis*, African horse sickness virus, Venezuelan equine encephalitis virus, epizootic lymphangitis caused by *Histoplasma farciminosum*, and *Taenia multiceps* (also known as *Taenia coenurus*).

In addition to the diseases listed above, we will consider the following diseases when determining conditions for the importation of animals and animal products: Akabane virus, bluetongue virus, epizootic hemorrhagic disease virus, malignant catarrhal fever virus (African or wildebeest form), blue eye disease of swine (paramyxovirus), *Brucella abortus, Brucella melitensis, Brucella suis, Trypanosoma vivax*, contagious agalactiae of sheep and goats due to *Mycoplasma agalactiae, Mycobacterium bovis*, pseudorabies, sheep pox and goat pox, heartwater due to *Cowdria ruminantium*, Japanese encephalitis virus, lumpy skin disease (Neethling virus), Nairobi sheep disease (Ganjam, Dugbe) virus, peste des petits ruminants, Rift Valley fever, and theileriosis (east coast fever, corridor disease, Mediterranean fever), turkey rhinotracheitis (swollen head), goose parvovirus (Derzsy's disease), adenovirus 127 (egg drop syndrome), *salmonella pullorum*, and *salmonella gallinarium*.

In determining conditions for the importation of animals, we will also consider the presence in the region of ectoparasites of animals if the ectoparasites are not known to exist in the United States or are subject to cooperative Federal/State control programs in the United States. These ectoparasites include the following:

*Ticks: Amblyomma astrion, A. cohaerens, A. gemma, A. hebraeum, A. javenese, A. lepidum, A. marmoreum, A. pomposum, A. sparsum, A. testudinarium, A. tholloni, A. variegatum, Boophilus annulatus, B. decoloratus, B. florae, B. geigyi, B. kohisi, B. microplus, Dermacentor daghestanicus, D. marginatus, D. nuttalli, D. pictus, D. reticulatus, D. silvarium, Haemaphysalis bispanosa, H. leachii, H. longicornis, H. otophila, H. punctata, H. sulcata, Hyalomma anatolicum anatolicum, H. anatolicum excavatum, H. detritum, H. dromedarii, H. marginatum marginatum, H. marginatum rufipes, H. marginatum turanicum, H. scupense, H. truncatum, Ixodes persulcatus, I. pilosus, I. ricinus, Ornithodoros erraticus, O. moubata, O. moubata porcinus, Rhipicephalus appendiculatus, R. bursa, R. capensis, R. compositus, R. evertsi evertsi, R. evertsi, mimeticus, R. glabroscutatum, R. kochi, R. lunulatus, R. pulchellus, R. simus, R. turanicus, and R. zambeziensis.*

*Mites: Chorioptes bovis*, various subspecies of which cause mange in horses, cattle, and sheep; *Psorergates ovis*, the causative agent of sheep scabies; *Psoroptes cuniculi*, the causative agent of ear mange in goats and rabbits; and *P. ovis*, various subspecies of which cause scabies and mange in horses, cattle, sheep, and swine.

*Insects: Chrysomyia bezziana* (Old World screwworm), *Cochliomyia hominivorax* (*Callitrogra americana*) (New World screwworm), and *Hippobosca* spp. and *Lipoptema* spp. (louse flies).

Done in Washington, DC, this 22nd day of October 1997.

**Terry L. Medley,**

*Administrator, Animal and Plant Health Inspection Service.*

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# Part V

# Department of Agriculture

## Agriculture Marketing Service

**7 CFR Parts 91, 93 and 96**

**Revision of Laboratory Service Fees; Proposed Rule**

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

### 7 CFR Parts 91, 93, and 96

**[Docket Number S&TD–97–001]**

### Revision of Laboratory Service Fees

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** The Agricultural Marketing Service (AMS) proposes to amend current fees and to add new fees for laboratory testing services for agricultural commodities. This proposed rule includes additional tests for various commodity products. This document reflects increased program costs including the cost-of-living adjustments since the last fee changes.

**DATES:** Comments must be received on or before November 28, 1997.

**ADDRESSES:** Interested persons are invited to submit comments concerning this proposed rule. Comments should be sent in triplicate to James V. Falk, Docket Manager, USDA, AMS, Science and Technology, P.O. Box 96456, Room 3517-South, Washington, DC 20090–6456 and should refer to the docket title and number located in the heading of this document. Comments received will be available for public inspection in Room 3507, South Agriculture Building, 1400 Independence Avenue, SW, between the hours of 10:00 a.m. and 4:00 p.m., Eastern Time, Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Dr. Alan R. Post, (202) 720–3322.

**SUPPLEMENTARY INFORMATION:** This proposed rule has been determined to be not significant for purposes of Executive Order 12866 and has not been reviewed by the Office of Management and Budget (OMB).

This proposal has been reviewed under Executive Order 12988, Civil Justice Reform. This action is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulation, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative procedures which must be exhausted prior to any judicial challenge to this rule or the application of its provisions.

### Regulatory Impact Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities.

There are more than 300 users of the Science and Technology Division's (S&TD) laboratory testing services. Many of these users are small entities under the criteria established by the Small Business Administration (13 CFR 121.601). The Administrator of AMS determined that this action would not have a significant economic impact on a substantial number of these small businesses because only minimal increases to user fees for laboratory tests for commodities are recommended. Laboratory tests and services of S&TD are provided to these businesses on a voluntary basis and any decision on their part to discontinue the use of the services and obtain new contracts with other governmental agency or private laboratories would not hinder the food processors from marketing their products. In fiscal year 1996, the S&TD Laboratory Program revenues exceeded obligatory costs by only $101,000. The decline in revenue from the fiscal year 1995 level of $907,000 was due to a decrease in the requested dairy product testing at the S&TD Midwestern Laboratory in Chicago, Illinois. For fiscal year 1997 the Science and Technology Division expects to report a $332,000 deficit at the current fee level because there were additional revenue declines with the analyzing of all other commodities at our laboratories. In 1997 the S&TD expects to incur revenue losses from 1996 levels of $216,000 and $449,000 respectively from poultry and tobacco product testing. In addition, the aflatoxin testing program net governmental receipts available to cover administrative costs and authorized appropriation outlays are projected to decline from $79,000 in 1996 to $14,000 in 1997. This is a consequence of the increased number of Peanut Administrative Committee (PAC) approved private laboratories that handle required aflatoxin analyses of peanuts. In recent years S&TD has voluntarily closed aflatoxin testing facilities at Camilla and Ashburn, Georgia. This was a streamlining measure to reduce Federal program costs and to restructure the Division to improve efficiency of operations and responsiveness of services. We expect the Laboratory Program to end fiscal year 1997 with an operating reserve of $3,261,000 which will provide a reserve balance below the 6 month reserve appropriate under normal operating conditions. The AMS estimates that overall this rule would yield additional laboratory testing program revenues of $694,000 during fiscal year (FY) 1998. Without the fee increase, anticipated revenue would not cover program costs. Projected FY 1998 laboratory revenues are $5,616,000 with obligatory costs projected at $6,276,000. Trust fund balances would be below the required 4 month reserve levels. With a fee increase, projected FY 1998 revenues would be $6,310,000 with obligatory costs projected at $6,276,000. The laboratory fees in the general schedules would increase by approximately 6 percent. These fees are competitive to the fees found in price lists distributed by private laboratories. Furthermore, users of S&TD testing services are under no obligation to use them. This proposed action updates lists of laboratory tests and services contained in certain sections of the regulations. In addition, the fees for the specialized and required aflatoxin testing of nuts and their products would have increases ranging from 6 to 21 percent.

### Paperwork Reduction Act

In accordance with the provisions of the Paperwork Reduction Act of 1980, as amended on May 22, 1995 (44 U.S.C. Chapter 35; Pub. L. 104–13 § 2), the information collection requirements contained in the provisions to be updated have been previously approved by the Office of Management and Budget.

No additional recordkeeping requirements are imposed as a result of this rule.

### Background

On August 9, 1993, AMS published a rule in the **Federal Register** (58 FR 42408—42448) to combine all AMS regulations concerning laboratory services. The goal was to consolidate and to transfer existing laboratory testing programs operating independently under the various commodity divisions (Cotton, Poultry, Fruit and Vegetable, Tobacco, Dairy, and Livestock and Seed) to its S&TD, formerly the Science Division. The rule included fees charged for testing and related services under the diversified S&TD programs and set the hourly analytical testing rate at $34.20 per hour. On May 10, 1994, an interim final rule was published in the **Federal Register** (59 FR 24318—24325) which was finalized on September 30, 1994 (59 FR 50120—50122) and which reduced S&TD laboratory testing fees for certain dairy products and established additional tests with fees for dairy products for incorporation into existing schedules.

The S&TD laboratory testing programs are mainly voluntary, user fee services, conducted under the authority of the Agricultural Marketing Act of 1946, as amended. However under certain

programs such as those involving peanuts, aflatoxin testing is required. The Act authorizes the Secretary of Agriculture to provide Federal analytical testing services that facilitate marketing and allow products to obtain grade designations or meet marketing standards. In addition, the laboratory tests establish quality standards for agricultural commodities. The Act also requires that reasonable fees be collected from the users of the services to cover as nearly as possible the costs of maintaining the programs.

There is a need to revise the list of testing services available due to changes in analytical methodologies and customer service needs. Under this proposed rule, new laboratory tests are added to the tables in Part 91 as follows: (1) Heavy metal screen, (2) niacin, (3) odor, (4) vitamin B–1 (thiamin), (5) vitamin B–2 (riboflavin), (6) capsaicin (hot sauce), (7) color (apparent-visual), (8) extractable color in spices, (9) hydroxymethylfurfural (honey), (10) linolenic acid, (11) overrun for whipping topping, (12) pH—quinhydrone (cheese), (13) serum drainage for whipped topping, (14) rate of wetting (nondairy creamer), (15) reducing sugars, (16) *Bacillus cereus*, (17) *Lactobacillus* count, (18) *Salmonella* enumeration (complete test), (19) *Salmonella typhi* (meat products), and (20) parasite identification. The direct microscopic clump count (DMCC) test is removed from Table 5 in Part 91 because it is analogous to the bacterial direct microscopic count test. Certain other laboratory tests are removed from the tables in Part 91 because there have been few, if any, requests for these tests in recent years. These outmoded laboratory tests are fat (cheese and related products), fat by specific gravity, moisture by Karl Fischer, and proteolytic count (dairy products). Four existing laboratory test fees in the tables of Part 91 are reduced corresponding to reduced analysis time and lowered equipment cost associated with utilizing revised methodology. The cholesterol test fee is lowered from $171.00 to $90.65. The available carbon dioxide test fee is reduced from $136.80 to $54.39. The jelly strength (bloom) test fee is reduced from $85.50 to $54.39. The water activity test is changed from $136.80 to $27.20.

In its analysis of projected costs for fiscal years 1997 and 1998, AMS has identified increases in the costs of providing laboratory testing services despite declining revenues. The total Laboratory Program obligations in FY 1996 were $5,963,000 while the program operating costs are projected to be $6,032,000 in FY 1997 with current fees. These cost increases are attributable mainly (65 percent of total operating budget or $3,684,000 in 1997) to national and locality pay raises and increased benefit costs for Federal employees. A general and locality salary increase for Federal employees, ranging from 3.09 to 6.25 percent depending on locality, effective January 1995, a general and locality salary increase for Federal employees, ranging from 2.39 to 2.89 percent depending on locality, effective January 1996, and an additional salary increase, ranging from 3.30 to 6.26 percent depending on localities, effective January 1997, has materially affected the costs of laboratory programs. Current and estimated demand for the laboratory services are also factored in the fee revisions. Since S&TD's last fee increase in August 1993 (58 FR 42408) total annual revenue of the S&TD's laboratories has decreased from $6.2 million to $5.6 million. Major factors affecting these revenue losses include industry's implementation of plant and in-house testing, cutbacks in dairy support and procurement programs, and reduction in USDA food assistance programs due to re-engineering involving State and local governments. It is anticipated that in FY 1998, at the current fee levels, the S&TD will not have sufficient revenue to sustain present staffing levels, to cover equipment and material cost increases, and to still maintain an adequate reserve balance of $2.7 million or a minimum 4 months reserve called for by Agency policy and prudent financial management.

The AMS laboratory testing programs are voluntary, user fee services, conducted under the authority of the Agricultural Marketing Act of 1946, as amended. The Act requires that reasonable fees be collected from the users of these services to cover, as nearly as practicable, the costs of maintaining the programs. A recent review of the current fee schedules, effective since September 30, 1994 (59 FR 50120—50122), revealed that anticipated revenue would not adequately cover increasing program costs. Without a fee increase, projected FY 1998 revenues for laboratory services are $5,616,000 with obligatory costs projected at $6,276,000. Accordingly, S&TD is proposing to increase by 6 percent the currently listed laboratory fees in Tables 1 through 5 and in Tables 7 through 8 in Part 91. The standard hourly rate would be increased from $34.20 to $36.26 (6 percent). In addition, the laboratory rate for appeals, holiday and overtime service would be raised from $51.30 to $54.39 per analysis hour.

The fees and charges in Part 96 involved with the official grading of any lot of cottonseed would also increase by 6 percent. These fee increases are needed because of a statistical based cottonseed lot size study by S&TD in 1992 and the consequential revision of rule 135, section 5 of the Trading Rules of the National Cottonseed Products Association. The trade association's rule allows licensed cottonseed samplers under AMS's supervision to increase the maximum cottonseed lot size from 150 to 300 tons to obtain a representative official cottonseed sample when prevailing environmental conditions during a period of 3 consecutive days do not compromise the quality of graded cottonseed. This resulted in a corresponding yearly reduction of the total number of official cottonseed samples subject to analytical chemical methods to derive a composite official grade designation. Even though the cottonseed chemist licensing program costs have been lowered in recent years, the loss of revenue resulting from the decreased issuance of the official cottonseed grading certificates has been substantial. Therefore, the Agency proposes to revise the certificate fee charged for official analysis and cottonseed grade determination from $3.00 per certificate, issued by the chemist, to $3.18. The application fee for a chemist's license would be raised from $1,100.00 to $1,166.00 for the examination, while the fee for renewal of the license would be increased from $275.00 to $292.00.

The laboratory fees for aflatoxin analyses in Table 6 in Part 91 would be increased or decreased depending on the commodity type or analytical method utilized. The cost of analyzing shelled peanuts by high performance liquid chromatography (HPLC) would be decreased from $50.00 to $31.00 per single analysis because automated HPLC equipment is being used now in the laboratory. Other aflatoxin test fees would increase by 6 to 21 percent because there are corresponding increased costs of the expendable supplies and materials to perform these analyses.

The rule would remove the time allotments for single tests in Tables 1 through 7 in Part 91. The time allotments stated in the prior rules and regulations of the S&TD (58 FR 42415, August 9, 1993 and 59 FR 50121, September 30, 1994) are no longer applicable because of the recent approval of automated equipment and rapid procedures for many of the listed tests. This new technology comes with

increased expenses in specialized supplies and materials required to perform the requested analyses.

This proposal provides for a 30-day comment period. This period is deemed appropriate in view of the need to make revisions to the current fee schedules without delay if approved.

**List of Subjects**

*7 CFR Part 91*

Administrative practice and procedure, Science and Technology Division Laboratories, Fees and charges

*7 CFR Part 93*

Citrus fruits, Fruit juices, Fruits, Laboratories, Nuts, Vegetables

*7 CFR Part 96*

Cottonseeds, Chemist's licensure, Cottonseed quality analysis, Official grade.

For the reasons set forth in the preamble, Title 7, chapter I is proposed to be amended as follows:

## PART 91—SERVICES AND GENERAL INFORMATION

1. The authority citation part 91 continues to read as follows:

**Authority:** 7 U.S.C. 1622, 1624.

### Subpart I—Fees and Charges

2. In § 91.37, Tables 1 through 8 and paragraph (b) are revised and a new paragraph (d) is added to read as follows:

**§ 91.37 Fees for laboratory testing, analysis, and other services.**

* * * * *

TABLE 1.—SINGLE TEST LABORATORY FEES FOR PROXIMATE ANALYSES

| Type of analysis | List fee |
|---|---|
| Ammonia, Ion Selective Electrode | $81.59 |
| Ash, Total | 36.26 |
| Ash, Acid Insoluble | 54.39 |
| Chloride, Salt Titration (Dairy) | 18.13 |
| Fat, Acid Hydrolysis | 36.26 |
| Fat (Dairy Products) | 18.13 |
| Fat, Ether Extraction | 36.26 |
| Fat, Microwave—Solvent Extraction | 36.26 |
| Fiber, Crude | 72.52 |
| Moisture, Distillation | 36.26 |
| Moisture, Oven | 18.13 |
| Protein, Kjeldahl | 72.52 |
| Salt, Back Titration | 27.20 |
| Salt, Potentiometric | 18.13 |

TABLE 2.—SINGLE TEST LABORATORY FEES FOR LIPID RELATED ANALYSES

| Type of analysis | List fee |
|---|---|
| Acid Degree Value (Dairy) | $36.26 |
| Acidity, Titratable | 9.07 |
| Carotene, Spectrophotometric | 90.65 |
| Catalase Test | 18.13 |
| Cholesterol [1] | 90.65 |
| Color (Honey) | 18.13 |
| Color, NEPA (Eggs) | 36.26 |
| Consistency, Bostwick (Cooked) | 18.13 |
| Consistency, Bostwick (Uncooked) | 18.13 |
| Density (Specific Gravity) | 9.07 |
| Dispersibility (Moates-Dabbah Method) | 18.13 |
| Fat Stability,[2] AOM | 36.26 |
| Fatty Acid Profile (AOAC–GC method) | 145.04 |
| Flash Point Test only | 72.52 |
| Free Fatty Acids | 18.13 |
| Meltability (Process Cheese) | 18.13 |
| Peroxidase Test | 18.13 |
| Peroxide Value | 27.20 |
| Smoke Point Test only | 72.52 |
| Smoke Point and Flash Point | 126.91 |
| Solids, Total (Oven Drying) | 18.13 |
| Soluble Solids, Refractometer | 18.13 |

[1] Moisture and fat analyses are required to be analyzed at an additional cost as prerequisites to the cholesterol test.
[2] Peroxide value analysis is required as a prerequisite to the fat stability test at the additional fee.

TABLE 3.—SINGLE TEST LABORATORY FEES FOR FOOD ADDITIVES
(DIRECT AND INDIRECT)

| Type of analysis | List fee |
|---|---|
| Aflatoxin, (Dairy, Eggs) | $126.91 |
| Alar or Daminozide Residue | 217.56 |
| Amitraz Residue, GLC | 217.56 |

TABLE 3.—SINGLE TEST LABORATORY FEES FOR FOOD ADDITIVES—Continued
(DIRECT AND INDIRECT)

| Type of analysis | List fee |
|---|---|
| Alcohol (Qualitative) | 72.52 |
| Alkalinity of Ash | 54.39 |
| Antibiotic, Qualitative (Dairy) | 18.13 |
| Antibiotic, Quantitative [1] | 398.86 |
| Ascorbates (Qualitative—Meats) | 18.13 |
| Ascorbic Acid, Titration | 36.26 |
| Ascorbic Acid, Spectrophotometric | 36.26 |
| Benzene, Residual | 72.52 |
| Brix, Direct Percent Sucrose | 18.13 |
| Brix, Dilution | 18.13 |
| Butylated Hydroxyanisole (BHA) | 54.39 |
| Butylated Hydroxytoluene (BHT) | 54.39 |
| Caffeine, Micro Bailey-Andrew | 54.39 |
| Caffeine, Spectrophotometric | 36.26 |
| Calcium | 54.39 |
| Citric Acid, GLC or HPLC | 54.39 |
| Chlorinated Hydrocarbons: | |
| Pesticides and Industrial Chemicals: | |
| Initial Screen | 145.04 |
| Second Column Confirmation of Analyte | 36.26 |
| 3Confirmation on Mass Spectrometer | 72.52 |
| Dextrin (Qualitative) | 18.13 |
| Dextrin (Quantitative) | 108.78 |
| Filth, Heavy (Dairy) | 90.65 |
| Filth, Heavy (Eggs) | 145.04 |
| Filth, Light (Eggs) | 90.65 |
| Filth, Light & Heavy (Eggs Extraneous) | 217.56 |
| Flavor (Dairy) | 9.07 |
| Flavor (Products except Dairy) | 27.20 |
| Fumigants: | |
| Initial Screen: | |
| Dibromochloropropane (DBCP) | 36.26 |
| Ethylene Dibromide | 36.26 |
| Methyl Bromide | 36.26 |
| Confirmation on Mass Spectrometer: | |
| Each individual fumigant residue | 72.52 |
| Glucose (Qualitative) | 27.20 |
| Glucose (Quantitative) | 63.46 |
| Glycerol (Quantitative) | 108.78 |
| Gums | 108.78 |
| Heavy Metal Screen [2] | 317.28 |
| High Sucrose Content or Avasucrol: | |
| Percent Sucrose (Holland Eggs) | 145.04 |
| Hydrogen Ion Activity, pH | 18.13 |
| Mercury, Cold Vapor AA | 90.65 |
| Metals—Other Than Heavy, Each Metal | 72.52 |
| Monosodium Dihydrogen Phosphate | 145.04 |
| Monosodium Glutamate | 145.04 |
| Niacin | 72.52 |
| Nitrites (Qualitative) | 18.13 |
| Nitrites (Quantitative) | 108.78 |
| Oxygen | 18.13 |
| Odor | 9.07 |
| Palatability and Odor: | |
| First Sample | 27.20 |
| Each Additional Sample | 18.13 |
| Phosphatase, Residual | 36.26 |
| Phosphorus | 72.52 |
| Propylene Glycol, Codistillation: | |
| (Qualitative) | 72.52 |
| Pyrethrin Residue (Dairy) | 145.04 |
| Scorched Particles | 9.07 |
| Sodium, Potentiometric | 36.26 |
| Sodium Benzoate, HPLC | 54.39 |
| Sodium Lauryl Sulfate (SLS) | 290.08 |
| Sodium Silicoaluminate (Zeolex) | 72.52 |
| Solubility Index | 18.13 |
| Starch, Direct Acid Hydrolysis | 108.78 |
| Sugar, Polarimetric Methods | 36.26 |
| Sugar Profile, HPLC: [3] | |
| One type sugar from HPLC profile | 108.78 |

TABLE 3.—SINGLE TEST LABORATORY FEES FOR FOOD ADDITIVES—Continued
(DIRECT AND INDIRECT)

| Type of analysis | List fee |
|---|---|
| Each additional type sugar | 18.13 |
| Sugars, Non-Reducing | 108.78 |
| Sugars, Total as Invert | 72.52 |
| Sulfites (Qualitative) | 27.20 |
| Sulfur Dioxide, Direct Titration | 36.26 |
| Sulfur Dioxide, Monier-Williams | 54.39 |
| Toluene, Residual | 72.52 |
| Triethyl Citrate, GC (Quantitative) | 36.26 |
| Vitamin A | 90.65 |
| Vitamin A, Carr-Price (Dry Milk) | 45.33 |
| Vitamin B–1 (Thiamin) | 72.52 |
| Vitamin B–2 (Riboflavin) | 72.52 |
| Vitamin D, HPLC (Vitamins $D_2$ and $D_3$) | 308.21 |
| Whey Protein Nitrogen | 27.20 |
| Xanthydrol Test For Urea | 54.39 |
| This is an optional test to the extraneous materials isolation test. | |

[1] Antibiotic testing includes tests for chlorotetracycline, oxytetracycline, and tetracycline.
[2] Heavy metal screen includes tests for cadmium, lead, and mercury.
[3] This profile includes the following components: Dextrose, Fructose, Lactose, Maltose and Sucrose.

TABLE 4.—SINGLE TEST LABORATORY FEES FOR OTHER CHEMICAL AND PHYSICAL COMPONENT ANALYSES

| Type of analysis | List fee |
|---|---|
| Available Carbon Dioxide (Baking Powders) | $54.39 |
| Capsaicin (Hot Sauce) | 72.52 |
| Color, Apparent-Visual | 9.07 |
| Complete Kohman Analysis (Dairy) | 36.26 |
| Extractable Color in Spices | 18.13 |
| Grape Juice Absorbency Ratio | 18.13 |
| Hydroxymethylfurfural (Honey) | 36.26 |
| Jelly Strength (Bloom) | 54.39 |
| Linolenic Acid | 72.52 |
| Methyl Anthranilate | 36.26 |
| Net Weight (Per Can) | 9.07 |
| Non-Volatile Methylene Chloride Extract | 90.65 |
| Overrun for Whipped Topping | 27.20 |
| Particle Size (Ether Wash) | 18.13 |
| pH—Quinhydrone (Cheese) | 18.13 |
| Potassium Iodide (Table Salt) | 54.39 |
| Quinic Acid (Cranberry Juice) | 63.46 |
| Serum Drainage for Whipped Topping | 18.13 |
| Sieve or Particle Size | 18.13 |
| Rate of Wetting (Nondairy Creamer) | 18.13 |
| Reducing Sugars | 72.52 |
| Water Activity | 27.20 |
| Water Insoluble Inorganic: Residues (WIIR) | 72.52 |
| Yellow Onion Test | 27.20 |

TABLE 5.—SINGLE TEST LABORATORY FEES FOR MICROBIOLOGICAL ANALYSES

| Type of analysis | List fee |
|---|---|
| Aerobic (Standard) Plate Count | $18.13 |
| Anaerobic Bacterial Plate Count | 27.20 |
| *Bacillus cereus* | 72.52 |
| Bacterial Direct Microscopic Count | 36.26 |
| *Campylobacter jejuni* | 145.04 |
| Coliform Plate Count (Dairy Products) | 18.13 |
| Coliform Plate Count, Violet Red Bile Agar (Presumptive Coliform Plate Count) | 27.20 |
| Coliforms, Most Probable Number (MPN): [1] | |
| Step 1 | 27.20 |
| Step 2 | 27.20 |
| *E coli,* Presumptive MPN (Additional) [2] | 54.39 |
| Enterococci Count | 108.78 |
| *Lactobacillus* Count [3] | 45.33 |
| *Listeria monocytogenes* Confirmation Analysis: [4] | |
| Step 1 | 54.39 |
| Step 2 | 54.39 |

TABLE 5.—SINGLE TEST LABORATORY FEES FOR MICROBIOLOGICAL ANALYSES—Continued

| Type of analysis | List fee |
|---|---|
| Step 3 (Confirmation) | 90.65 |
| Parasite Identification | 145.04 |
| Psychrotrophic Bacterial Plate Count | 27.20 |
| *Salmonella* (USDA Culture Method): [5] | |
| Step 1 (Dairy Products) | 36.26 |
| Step 1 | 54.39 |
| Step 2 | 27.20 |
| Step 3 (Confirmation) | 54.39 |
| Serological Typing (Optional) | 90.65 |
| *Salmonella* Enumeration (Complete Test) | 108.78 |
| *Salmonella* (Rapid Methods): [6] | |
| Step 1 | 72.52 |
| Step 2 | 27.20 |
| Step 3 (Confirmation) | 54.39 |
| *Salmonella typhi* (Meat Products) [7] | 36.26 |
| *Staphylococcus aureus,* MPN: | |
| With Coagulase Positive Confirmation | 63.46 |
| Thermoduric Bacterial Plate Count | 27.20 |
| Yeast and Mold Count | 18.13 |
| Yeast and Mold Differential Plate Count | 27.20 |

[1] Coliform MPN analysis may be in two steps as follows: Step 1—presumptive test through lauryl sulfate tryptose broth; Step 2—confirmatory test through brilliant green lactose bile broth.

[2] Step 1 of the coliform MPN analysis is a prerequistite for the performance of the presumptive *E. coli* test. Prior enrichment in lauryl sulfate tryptose broth is required for optimal recovery of *E. coli* from inoculated and incubated EC broth (*Escherichia coli* broth). The *E. coli* test is performed through growth on eosin methylene blue agar. The fee stated for *E. coli* analysis is a supplementary charge to step 1 of coliform test.

[3] Determination of bacterial plate count of different species of *Lactobacillus.*

[4] *Listeria monocytogenes* test using the USDA method may be in three steps as follows: Step 1—isolation by University of Vermont modified (UVM) broth and Fraser's broth enrichments and selective plating with Modified Oxford (MOX) agar; Presumptive Step 2—typical colonies inoculated from Horse Blood into brain heart infusive (BHI) broth and check for characteristic motility; Confirmatory Step 3—culture from BHI broth with typical motility is inoculated into the seven biochemical medias, BHI agar for oxidase and catalase tests, Motility test medium, and Christie-Atkins-Munch-Peterson (CAMP) test. *Listeria monocytogenes* test using the FDA method may be in three steps as follows: Step 1—isolation by trypticase soy broth with 0.6% yeast extract (TSB–YE) broth enrichment and selective plating with Modified McBrides agar and Lithium chloride Phenylethanol Moxalactam (LPM) agar; Presumptive Step 2—typical colonies inoculated to trypticase soy agar with yeast extract (TSA–YE) with sheep blood plates to check for hemolysis followed by inoculations to BHI broth and TSA–YE plates to check for characteristic motility, gram stain and catalase test; Confirmatory Step 3—culture from BHI broth with typical motility for wet mount is inoculated into the required 10 biochemical medias, Sulfide-Indole-Motility (SIM) medium, and the CAMP test. Serology is checked using growth from TSA–YE plates. Both methods for *Listeria determination have the equivalent time needed for each step.*

[5] *Salmonella* test may be in three steps as follows: Step 1—growth through differential agars; Step 2—growth and testing through triple sugar iron and lysine iron agars; Step—3 confirmatory test through biochemicals, and polyvalent serological testing with Poly ''O'' and Poly ''H'' antiserums. The serological typing of *Salmonella* is requested on occasion.

[6] *Salmonella* test may be in three steps as follows: Step 1—growth in enrichment broths and ELISA test or DNA hybridization system assay; Step 2—growth and testing through triple sugar iron and lysine iron agars; Step 3—confirmatory test through biochemicals, and polyvalent serological testing with Poly ''O'' and Poly ''H'' antiserums.

[7] *Salmonella typhi* determination in mechanically deboned meat.

TABLE 6.—LABORATORY FEES FOR AFLATOXIN ANALYSES

| Aflatoxin test by commodity | Fee per single analysis | Fee per pair analyses [1] |
|---|---|---|
| Peanut Butter (TLC—CB—Affinity Column) | $36.26 | NA [2] |
| Corn (TLC—CB—Affinity Column) | 36.26 | NA |
| Roasted Peanuts (TLC—BF) | 36.26 | NA |
| Brazil Nuts (TLC—BF) | 72.52 | NA |
| Pistachio Nuts (TLC—BF) | 72.52 | NA |
| Shelled Peanuts (TLC—Affinity Column) | 17 | 34 |
| Shelled Peanuts (HPLC) | 31 | 62 |
| Tree Nuts (TLC) | 36.26 | NA |
| Oilseed Meals (TLC) | 36.26 | NA |
| Edible Seeds (TLC) | 36.26 | NA |
| Dried Fruit (TLC) | 36.26 | NA |
| Small Grains (TLC) | 36.26 | NA |
| In-Shell Peanuts (TLC) | 17 | 34 |
| Silage; Other Grains (TLC) | 36.26 | NA |
| Submitted Samples (TLC—Affinity Column) | 36.26 | NA |

[1] Aflatoxin testing of raw peanuts under Peanut Marketing Agreement for subsamples 1–AB, 2–AB, 3–AB, and 1–CD is $34.00 per pair of analyses using Thin-Layer Chromatography (TLC) and Best Foods (BF) extraction or immunoaffinity column chromatography method. The BF method has been modified to incorporate a water slurry extraction procedure. The Contaminants Branch (CB) method is used on occasion as an alternative method for peanuts and peanut meal when doubt exists as to the effectiveness of the Best Foods method in extracting aflatoxin from the sample or when background interferences exist that might mask TLC quantitation of aflatoxin. The cost per single or pair of analyses using High Pressure Liquid Chromatography (HPLC) is $31.00 and $62.00, respectively. Other aflatoxin analyses for fruits and vegetables are listed at Science and Technology Division's current hourly rate of $36.26.

[2] NA denotes not applicable.

TABLE 7.—MISCELLANEOUS CHARGES SUPPLEMENTAL TO THE SCIENCE AND TECHNOLOGY DIVISION'S LABORATORY ANALYSIS FEES

| Laboratory service description | List fee |
|---|---|
| Sample Grinding Raw Peanuts by Vertical Cutter Mixer (VCM) | $18.13 |
| Sample Grinding Canned Boned Poultry (VCM) | 36.26 |
| Sample Grinding (Meats, Meat Products, Meals, Ready-to-Eat): | |
| per pouch or raw sample | 9.07 |
| per tray pack | 18.13 |
| Compositing Multiple Subsamples for an Individual Test Sample Unit per subsample | 9.07 |

TABLE 8.—ADDITIONAL CHARGES APPLICABLE TO THE SAMPLE RECEIPT AND ANALYSIS REPORT

| Service description | List charge |
|---|---|
| Established Courier Expense at Albany, Georgia S&TD Laboratory | $2.15 |
| Courier Expense at Other AMS Laboratories: | |
| Mileage Charge Set at $0.31 Per Mile Roundtrip from Laboratory to Delivery Site | Varies |
| Facsimile Charge (Per Analysis Report) | $3.20 minimum up to first 3 pages, then $1.10 per page |
| Additional Analysis Report or Extra Certificate (½ hour charge) | $18.13 per report or certificate reissued |

(b) The fee charge for any laboratory analysis not listed in paragraph (a) of this section, or for any other applicable services rendered in the laboratory, shall be based on the time required to perform such analysis or render such service. The standard hourly rate shall be $36.26.

* * * * *

(d) When Science and Technology Division provides applied and developmental research and training activities for microbiological and chemical analyses on agricultural commodities the applicant will be charged a fee on a reimbursable cost basis.

3. Section 91.38 is revised to read as follows:

**§ 91.38 Additional fees for appeal of analysis.**

(a) The appellant will be charged an additional fee at a rate of 1.5 times the standard rate stated in § 91.37(a) if, as a result of an authorized appeal analysis, it is determined that the original test results are correct. The appeal laboratory rate is $54.39 per analysis hour.

(b) The appeal fee will be waived if the appeal laboratory test discloses that an inadvertent error was made in the original analysis.

4. In § 91.39, paragraph (a) is revised to read as follows:

**§ 91.39 Special request fees for overtime and legal holiday service.**

(a) Laboratory analyses initiated at the special request of the applicant to be rendered on Saturdays, Sundays, Federal holidays, and on an overtime basis will be charged at a rate of 1.5 times the standard rate stated in § 91.37(a). The premium laboratory rate for holiday and overtime service will be $54.39 per analysis hour.

* * * * *

5. In § 91.40, paragraph (a) is revised to read as follows:

**§ 91.40 Fees for courier service and fasimile of the analysis report.**

(a) The AMS peanut aflatoxin laboratory at Albany, Georgia, has a set courier charge of $2.15 per trip to retrieve the sample package. The mileage charge specified in Table 8 of this part for courier service at other AMS laboratories is based on the shortest roundtrip route from laboratory to sample retrieval site.

* * * * *

## PART 93—PROCESSED FRUITS AND VEGETABLES

1. The authority citation part 93 continues to read as follows:

**Authority:** 7 U.S.C. 1622, 1624.

### Subpart B—Peanuts, Tree Nuts, Corn and Other Oilseeds

2. In § 93.11, the definition for ''aflatoxin'' is revised to read as follows:

*Aflatoxin.* A toxic metabolite produced by the molds *Aspergillus flavus, Aspergillus parasiticus,* and *Aspergillus nomius.* The aflatoxin compounds fluoresce when viewed under UV light as follows: aflatoxin $B_1$ and derivatives with a blue fluorescence, aflatoxin $B_2$ with a blue-violet fluorescence, aflatoxin $G_1$ with a green fluorescence, aflatoxin $G_2$ with a green-blue fluorescence, aflatoxin $M_1$ with a blue-violet fluorescence, and aflatoxin $M_2$ with a violet fluorescence. These closely related molecular structures are referred to as aflatoxin $B_1$, $B_2$, $G_1$, $G_2$, $M_1$, $M_2$, $GM_1$, $B_{2a}$, $G_{2a}$, $R_0$, $B_3$, $1–OCH_3B_2$, and $1–CH_3G_2$.

3. In § 93.12, paragraph (b)(1) is revised to read as follows:

**§ 93.12 Analyses available and locations of laboratories.**

* * * * *

(b) * * * (1) The Science and Technology Division Aflatoxin Laboratories at Albany and Blakely, Georgia will perform other analyses for peanuts, peanut products, and a variety of oilseeds. The analyses for oilseeds include testing for free fatty acids, ammonia, nitrogen or protein, moisture and volatile matter, foreign matter, and oil (fat) content.

* * * * *

## PART 96—COTTONSEED SOLD OR OFFERED FOR SALE FOR CRUSHING PURPOSES (CHEMICAL ANALYSIS AND UNITED STATES OFFICIAL GRADE CERTIFICATION)

1. The authority citation part 96 continues to read as follows:

**Authority:** 7 U.S.C. 1622, 1624.

2. Section 96.20 is revised to read as follows:

**§ 96.20 Fee for chemist's license.**

(a) The fee for the examination of an applicant for a license as a chemist to analyze and certify the grade of cottonseed shall be $1,166.00.

(b) The examination fee shall be paid at the time the application is filed or at a time prior to the administration of the

examinations. This fee shall be paid regardless of the outcome of the licensing examinations. The examination fee shall be nonrefundable to the applicant; however, in the evident of death of the applicant prior to the examination, full payment of the fee may be returned to the applicant's beneficiary. If an application is filed with an insufficient fee, the application and fee submitted will be returned to the applicant.

(c) For each renewal of a chemist's license, the fee shall be $292.00.

3. In § 96.21, paragraph (a) is revised to read as follows:

**§ 96.21 Fee for certificates to be paid by licensee to Service.**

(a) To cover the cost of administering the regulations in this part, each licensed cottonseed chemist shall pay to the Service $3.18 for each certificate of the grade of cottonseed issued by the licensee.

* * * * *

Dated: October 17, 1997.

**Lon Hatamiya,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. 97–28454 Filed 10–27–97; 8:45 am]

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federal register

Tuesday
October 28, 1997

# Part VI

# The President

## Proclamation 7045—National Consumers Week, 1997

Federal Register
Vol. 62, No. 208
Tuesday, October 28, 1997

# Presidential Documents

**Title 3—**

**The President**

**Proclamation 7045 of October 24, 1997**

## National Consumers Week, 1997

**By the President of the United States of America**

**A Proclamation**

Americans have always had a passion for fairness. It imbues the great charters on which our Nation is founded, and it is the cornerstone of our legal system. Fairness must also form the foundation of the American economy, an economy in which consumers rightly expect a ''fair shake'': honest transactions and safe, dependable goods and services.

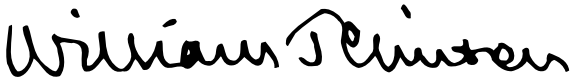
Our economy has changed enormously during the past 200 years, developing from the agrarian system of the 18th century through the Industrial Revolution of the 19th century to the information revolution of our own era. Today, technological innovation is rapidly transforming our relationships with the marketplace and the goods and services we buy. However, despite these dramatic changes, basic consumer values remain the same. Consumers still expect quality and service for their money; they still place great importance on the safety and reliability of the products they buy; and they still want to know that businesses will meet these expectations.

In the days of Adam Smith, when products were less complicated and their quality more easily discerned, *caveat emptor* was the ruling principle of the marketplace. In today's economy, where the microchip has dramatically altered what we buy and how and where we buy it, products and services are much more complex, and consumers need better information and greater protection to ensure that the marketplace continues to treat them fairly.

The Consumer Bill of Rights, first articulated in President Kennedy's 1962 Special Message to Congress on Protecting the Consumer Interest, has evolved with our economy to meet the changing needs of the American people. Consumers today have the right to safety, the right to information, the right to choice, the right to be heard, the right to consumer education, and the right to service. They also deserve security for any personal information provided during the conduct of a transaction, whether in person or on the Internet. As we observe National Consumer Week, I urge the American people to learn more about their rights as responsible consumers and to reward those businesses that continue to give them a fair shake.

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 25 through October 31, 1997, as National Consumers Week. I call upon government officials, industry leaders, and the American people to recognize the vital relationship between our economy and our citizenry, and to join me in reaffirming our commitment to fairness in the marketplace.

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



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  - Correction; published 8-11-97

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  - Restored copyright, notices of intent to enforce; corrections procedure; published 10-28-97

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## LIST OF PUBLIC LAWS

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**H.J. Res. 97/P.L. 105–64**

Making further continuing appropriations for the fiscal year 1998, and for other purposes. (Oct. 23, 1997; 111 Stat. 1343)

**Last List October 24, 1997**

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